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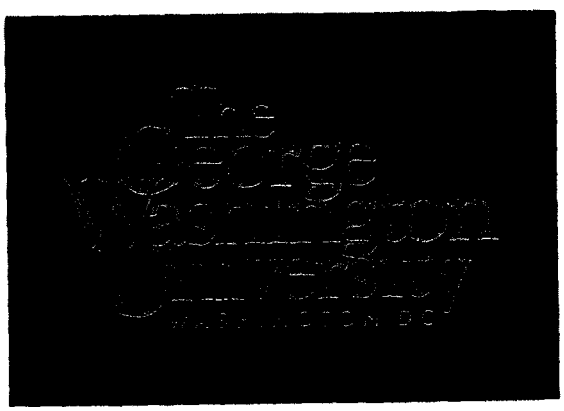
THE CENTER for HEALTH POLICY RESEARCH



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IMMUNIZATION IN THE UNITED BTATES:

A COMPENDIUM *OF* FEDERAL IMMUNIZATION LAWS AND PROGRAMS

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THE
CENTER
for
HEALTH POLICY RESEARCH

The George Washington University
WASHINGTON DC

EXECUTIVE SUMMARY

The National Vaccine Program Office, implementing recommendations of the Congressionally appointed National Vaccine Advisory Committee, asked The George Washington University, Center for Health Policy Research to review federal laws pertaining to immunization of children and adults in the civilian sector (with the exception of the National Vaccine Compensation Act) and assess ways in which their federal administration might be improved. This request grew out of the NVAC's 1992 report on barriers to access to immunizations and out of efforts by numerous federal agencies to develop an Interagency Action Plan.

This Compendium reviews more than 50 federal laws affecting the provision of immunization to children and adults in the United State. The laws reviewed here fall into five major categories: regulatory, financing, service delivery, case-finding and demonstrations. It makes recommendations of ways in which federal administration of these programs can be improved and strengthened. Key findings and recommendations are summarized in Part One. Individuals chapters on the laws reviewed are found in Part Two.

Chief among these recommendations are those made for the Health Care Financing Administration (the federal agency which administers Medicaid) the United States Public Health Service (which administers numerous programs providing subsidized vaccine services to low income and medically underserved persons), the Agency for Children and Families (which administers Aid to Families with Dependent Children) and the Department of Agriculture (which administers the Supplemental Food Programs for Women, Infants and Children). Together these programs form the bulk of the federal government's immunization activities. Important recommendations are also made for the Department of Labor, the Internal Revenue' Service, and the Office of Personnel Management, which oversees private insurance for both private sector employees and federal employees.

Medicaid: Current federal administration of the Medicaid immunization requirement for children can be strengthened in four specific areas: delineation of explicit coverage and frequency standards; delineation of what constitutes reasonable reimbursement standards; prohibitions against diverting vaccines meant for use by uninsured children and adults as a subsidy to state programs in lieu of discounted payment for vaccines; and comprehensive contract and quality of care standards for managed care plans.

Public Health Service: PHS should assure that its discount purchasing program, now securely in place for only one of the PHS vaccine programs, covers all vaccines purchased for public administration by any agency or program within the PHS as well as

by Medicaid and Medicare. This means extending the federal vaccine contracts to all federally purchased vaccines and establishing statewide distribution systems for all public payers.

WIC and AFDC: A major initiative is needed to assure that all children and adults receiving WIC or AFDC receive comprehensive patient education about the importance of immunizations and assistance in obtaining services. Federal standards to promote co-location of services whenever possible are needed.

OPM: The Office of Personnel Management should undertake a comprehensive review of all contracts with insurers to determine whether they offer comprehensive coverage for vaccine services. Vaccine coverage improvements should be made a high priority as OPM reviews insurance plans annually.

IMMUNIZATION IN THE UNITED STATES:

A COMPENDIUM OF FEDERAL IMMUNIZATION LAWS AND PROGRAMS

Prepared for the United States Public Health Service,
National Vaccine Program Office

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I. OVERVIEW

Immunization is a window into the soul of federal health law, policy, and practice. As with all other health care in the United States, there is no basic legal right to immunization; indeed, immunization services are funded and delivered through the same shaky private and governmental patchwork that is responsible for health care in this country generally. Health professionals, policy makers and families consider immunizations vital for children and an essential safeguard for the entire American population. Yet in an era of advances in medicine beyond anything considered possible even a generation ago, only between 70 and 80 percent of all American two-year-olds are fully immunized against childhood disease. In some of the nation's largest cities, that number dips to 40 percent.

No health service deserves greater federal policy attention and scrutiny than immunizations. Over the past decade the nation has witnessed a significant erosion in the immunization status of its youngest and most vulnerable children.[1] Eroding childhood immunization levels have had major implications for the health of children and for the cost of health care. As the National Vaccine Advisory Committee stated in a 1991 report to the Secretary,[2] the price of the measles epidemic that swept the nation between 1989

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[1] Freeman, Phyllis and Johnson, Kay "Health Challenge for the States: Achieving the Full Benefit of Childhood Immunizations" University of Massachusetts, Law Center, 1992.

[2] National Vaccine Advisory Committee. (April 22, 1992). Access to Childhood Immunizations: **Recommendations and Stratesies for Action**. **Dept.** of **Health and** Human Services, Washington, D.C.

and 1991 has been enormous. Not only were there more than 27,000 cases of measles and scores of child deaths reported, but the nation also spent billions of dollars it could ill afford. Each preventable case of measles serves as a testament to potential lost opportunities at the federal level to shape and direct the American health system in order to promote the health and well being of the population.

In searching for the reasons that explain these statistics it is natural to assess the performance of federal programs and to look for ways to strengthen them. This Compendium, prepared for the National Vaccine Program Office and the Congressionally mandated National Vaccine Advisory Committee, provides detailed information on 58 separate federal laws that finance, provide, and identify children and adults in need of, immunizations.[3] It analyzes federal agency immunization policies and guidance pertaining to these laws and makes a number of recommendations to improve federal programs and practices.

Some of the laws analyzed in this Compendium may appear to have little or nothing to do with immunizations. However, these laws, such as the Internal Revenue Code and the Employee Retirement Income and Security Act (ERISA), form the legal linchpins of the American health care system. Indeed, they play a major role in determining the scope and quality of private health insurance

[3] Pursuant to instructions from the NVPO, this compendium does not address the impact of the National Vaccine Compensation Act or federal laws pertaining to immunization services for active or retired members of the military and their dependents.

coverage. At a time when the cost of immunizing a child against preventable disease approaches $500 health insurance coverage for immunizations can make a critical difference in children's timely access to services. This is particularly true since young American families with children -- who are most likely to have young children -- have the lowest incomes of all American families.[4]

As they do with other forms of health care in the United States, federal laws have a considerable impact on the availability, affordability and accessibility of immunization services. Federal law can assure a steady supply of low cost vaccine. It can fund programs and services in medically underserved communities that have insufficient sources of primary health services. It can help develop innovative case-finding efforts to identify children and adults in need of immunizations. The government exercises this influence through statutes, regulations, interpretive guidance and program administration.

Federal immunization law, like federal other federal health laws, atop the modern American health care system much like the apex of a pyramid. National health policy derives much of its structure from the shape and scope of private sector programs and activities. An additional, powerful factor are the state and local laws that regulate the practice of health care and its financing. But federal law plays a significant role in determining where and how health care is practiced, and its quality and affordability.

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[4] Clifford Johnson, Andrew Sum and James D. Weill, Vanishing Dreams: The Economic Pliaht of America's Youns Families (Children's Defense Fund, Washington, D.C., 1992).

Federal tax and regulatory law create incentives to insure families. Federal law also establishes programs to fill some of the gaps left by the private insurance system. Federal laws setting qualification standards for health care institutions heavily influence how the quality of health care is judged.

Immunizations reflect this interplay between federal law, state laws, and private practice. Several federal statutes such as Medicare and Medicaid directly finance immunization services for persons who otherwise might be completely uninsured privately. Other federal laws, such as the community health centers program and the Title V Maternal and Child Health Services Block Grant, provide funds to establish and support programs that furnish subsidized health care, including immunizations, to low income and medically underserved children and adults. Numerous other laws, such as Aid to Families with Dependent Children (AFDC), the Supplemental Food Program for Women, Infants and Children (WIC), and Head Start, provide natural opportunities for identifying children and families in need of immunizations.

In administering federal programs, agencies must be able to take into account changing clinical standards and community health needs and continuously revise programs to keep them current and responsive. In addition, the complex set of relationships between federal law, state law, and "privately ordered" health care arrangements dictates that federal health laws be written broadly, with considerable implementation discretion vested in federal agencies.

For example, the Medicaid statute does not list each specific vaccine that state Medicaid agencies must provide to children. It would be far too cumbersome to have to re-enact the statute each time a new vaccine is added to the recommended childhood immunization schedule. Instead, the law itself simply requires states to pay for all medically necessary childhood immunizations. The Secretary of Health and Human Services has both the general and specific authority (and the duty) to establish, oversee, and enforce more specific compliance standards. This is done through agency regulations and interpretive guidance.

The degree to which federal agencies elect to make use of their administrative powers varies greatly and depends on many factors. Some of the most important are the degree of prescription contained in each federal law, the degree of direct federal intervention and control contemplated by Congress, the body of federal/private and federal/state relationships, traditions and practices on which each federal law rests, and the extent to which any federal law is perceived as retaining a role for significant governmental direction at the state and community level. It is also fair to say that federal agency action reflects the general philosophy of federal governance held by a particular President and key Administration officials.

One would expect more rigorous federal standards and oversight in the case of directly federally administered programs (such as community health centers, family planning, or Head Start) than in the case of federal grant-in-aid supplements to state health **agency**

activities (such as the Preventive Health Services Block Grant)s. Similarly, one would anticipate far greater federal prescription in the case of federal programs involving mandated federal spending on a large scale (such as Medicaid) or in the case of federal initiatives to deal with very specific problems. Less federal prescription might be anticipated in the case of programs designed as general funding supplements to ongoing state-based activities (e.g., the Title V Maternal and Child Health Services Block Grant). But even where federal statutes appear to contemplate relatively modest direct federal regulation, the highly interconnected nature of the health care system demands that federal agency health policies be clear, comprehensive, and well coordinated.

Although it is possible to assess each federal program in this Compendium by itself, it is important to step back and consider the total impact of all of the programs reviewed here. Federal laws and programs affect each other. For example, federal laws pertaining to private health care financing and insurance help determine how well the nation's public immunization system functions. Good private coverage for immunizations helps promote access to services from private sector providers, thereby 'reducing the number of children and adults who depend on the subsidized services of an already overburdened public sector. Thus, even federal agencies that deal only with the private health sector have a potential role to play in improving the performance of public immunization programs.

The laws and programs which are described in greater detail in Part Two of this Compendium are listed on Tables 1 and 2 of this Overview. They can be divided into five basic groups:

1. laws that govern or regulate private insurance and the activities of private health care providers;
2. laws that finance health care though mandated third party payment arrangements (i.e., public health insurance for elderly and disabled persons, poor children and families, and federal agency workers);
3. laws that directly finance immunization services, particularly in low income and medically underserved communities with limited access to privately financed and privately delivered immunization services;
4. laws that support programs which can help identify persons (particularly children) in need of immunizations; and
5. federal demonstration programs that test new ways to improve the availability of immunizations and the immunization status of children.

Each individual chapter in Part Two of this Compendium describes a particular program or related cluster of programs and identifies opportunities available to federal agencies to improve and strengthen immunization program performance. This Overview summarizes these program-specific recommendations. It also offers a greater discussion of recommendations for several federal

programs -- Medicaid, WIC, AFDC, and health service programs administered by the United States Public Health Service -- that play a particularly significant role in determining the scope and quality of the nation's immunization effort.

PROGRAM RECOMMENDATIONS

In General: Tables 3 through 7 summarize our principal recommendations for individual federal programs. These recommendations are displayed in accordance with the broad categories set out above. Many of these recommendations pertain to ways in which federal agencies administering financing, health service and case-finding programs can strengthen inter-program relationships. For example, there are numerous recommendations for improving the relationship between Medicaid (the largest source of public funding for immunizations for low income children and adults) and programs administered by the Public Health Service because of the modest grant appropriations they receive, these programs depend to a great degree on Medicaid funding to help pay for the cost of furnishing care to their patients, virtually all of whom are poor.

Similarly, federal agencies administering health service programs need to expand and clarify their standards for linkage and referral arrangements between federally assisted service programs and case-finding programs such as child care, Head Start, child welfare services, public assistance and WIC. An example is increased federal guidance to state agencies receiving Title V MCH

Services Block Grant funding regarding minimum required linkages between Title V programs and local AFDC welfare offices. These arrangements might include stationing health educators or nursing staff in local welfare offices to conduct on-site health education and outreach, assigning individual patient case managers for particularly high risk families in need of immunizations and other health care, and training AFDC case workers on how to determine families' need for immunization assistance and provide referral assistance.

Many of the recommendations contained in this Compendium are predicated on the belief that within current law, federal agencies have considerable flexibility to exert additional influence over the size and shape of both public and private sector immunization activities. Agencies such as the Office of Personnel Management (OPM), the Department of Labor (DOL), and the Internal Revenue Service(IRS) potentially can help reduce the burden on publicly funded immunization programs through active efforts to promote broader immunization coverage within private insurance. Neither the IRS nor the Department of Labor may have either the legal authority to require comprehensive immunization coverage by employers as an ERISA performance or Internal Revenue Code compliance matter (although it is not clear that these agencies do not in fact possess considerable authority to establish minimum coverage standards: they just never have done so). Moreover, while the Office of Personnel Management may not have the power to prescribe minimum immunization coverage standards for all plans

that wish'to contract with the federal government, its bargaining clout is considerable. DOL and the IRS could do much with employers to actively encourage comprehensive immunization coverage. And OPM does use its considerable bargaining position (it is, after all, an $11 billion purchaser of health care) to promote certain types of health plan coverage.

While there are almost limitless possible recommendations for strengthening the multitude of federal programs that affect immunizations in one way or another, several federal programs stand far above all others and deserve particularly careful attention. These programs are of paramount importance to the nation's low income and medically underserved children and families, who are the most at risk for inadequate immunization. Indeed, the recent measles epidemic underscores the relationship between poverty, medical underservice, and preventable disease.

Medicaid: The first program is Medicaid. In 1990 the program reached one out of nearly every four children under age 6. That number is expected to grow, as childhood poverty remains elevated and Medicaid coverage of all children under age 6 with family incomes under 133 percent of the federal poverty level reaches full implementation.

The Medicaid statute requires that all states cover all medically necessary childhood immunizations as part of their Early and Periodic Screening Diagnosis and Treatment (EPSDT) programs. States must also, as part of EPSDT, assure that children receiving using EPSDT services receive timely treatment. The statute vests

the Health Care Financing Administration with wide-ranging authority to issue comprehensive Medicaid immunization standards and enforce state compliance with these standards. However, as discussed at greater length in the Medicaid chapter in Part Two, **HCFA's** rules and guidance are notable for their ambiguity and incompleteness. As a result, many states' EPSDT immunizations programs are inadequate.

The weaknesses of federal Medicaid policies fall into several distinct categories. First, there are neither comprehensive regulations nor interpretive guidance specifying the amount, duration and scope of required state immunization coverage. Many states are not covering all medically necessary childhood immunizations, even though the statute is absolutely clear in its requirement that they do so as a condition of federal financial participation. Moreover, there is virtually no guidance on recommended immunization coverage standards for adults, including pregnant women for whom immunizations arguably constitute a required, pregnancy-related service.

Second, despite the fact that the statute requires reasonable payment levels for all pediatric services, there are neither federal rules nor guidance on minimum reasonable state payment standards for vaccines and their administration. Nor, conversely, are there requirements for states to institute cost efficient discount purchasing arrangements and vaccine replacement programs to assure that vaccines are obtained at the lowest possible price and distributed in the most efficient fashion to participating

providers.

Thus, even where states' coverage standards are apparently sufficient, many do not reimburse sufficiently for immunization services. In some cases, reimbursement levels are well below the cost of the vaccine alone. In others, the cost of acquiring the vaccine may be covered, but virtually no payment is made for administration. These serious funding problems persist, without any HCFA guidance regarding reasonable immunization payment levels, even though the federal statute contains strong reimbursement requirements for pediatric services under Medicaid.

Third, the lack of clear HCFA policy means that some states may be largely avoiding their vaccine payment responsibilities altogether. It appears that rather than developing discounted purchasing arrangements for the vaccines their providers need, some state Medicaid programs instead are diverting CDC-provided vaccines meant for use by health providers serving uninsured low income uninsured children and adults. When Medicaid agencies (which by law must cover and pay for vaccines), consume the free supplies intended for the uninsured poor, this severely limits state health agencies' ability to reach many of their most vulnerable Medicaid-ineligible populations such as undocumented individuals and families and high risk children and adults ineligible for medical assistance.

Arguably in states with universal, free immunization programs, Medicaid is exempt from payment for immunizations. But fewer than ten states maintain universal systems under which immunizations are

furnished free of charge to all families regardless of their income or insurance status. Most states use income-related fee schedules to determine families' eligibility for reduced cost immunizations and bill insurers when available. In these states, Medicaid is not exempt from payment.

Consumption by Medicaid programs of free vaccines meant for the uninsured is a short-sighted approach to public immunization policy. But this practice also arguably violates the statute. Medicaid requires states to pay for immunizations. The use of free federal vaccine supplies by state Medicaid programs in lieu of discount purchasing arrangements means that scarce Public Health Service are being used to subsidize state Medicaid programs and supplant immunization funds that states are obligated to provide.

Finally is the challenge posed by managed care. Despite the enormous growth of Medicaid managed care arrangements and the need for clear quality and performance standards, HCFA has issued no comprehensive contract and quality of care performance rules in the area of immunizations. This is a matter of gravest concern as states increasingly privatize their Medicaid programs through broad-ranging contracts with managed care plans.

At least one major urban measles epidemic among young children already has been traced to the non-provision of immunization services by Medicaid HMOs.[5] There is evidence that state Medicaid managed care contracts fail to spell out express immunization

[5] Schlenker, T. & Fessler, K. (1990). Measles in Milwaukee. Wisconsin Medical Journal, 89, 403-407.

duties and coverage requirements on the part of plans; at least some states appear to permit plans to refer children elsewhere for immunization services rather than immunizing them on-site, even though immunizations are incidental to routine office visits and even though plans are being paid to provide comprehensive care.[6]

Medicaid managed care also has major implications for immunization services offered by state and local health agencies. The growth in Medicaid, accompanied by declining real-dollar public grant levels, means that many state and local health agencies now depend on Medicaid revenues to support many of their essential community health services. Medicaid managed care may change this. It is unclear whether either agency -- the Public Health Service or HCFA -- has carefully considered the implications of this change.

In managed care arrangements, patients (in this case, Medicaid patients) are required to receive all care and services through a single provider system. Care and services not furnished or authorized by the patient's managed care plan are no longer reimbursed by Medicaid, at least to the extent that the care sought falls into one of the categories of services covered under the managed care plan contract. While community health centers, public health agencies, Head Start programs, and other key providers of immunization services have relied on Medicaid to help pay for the

[6] The information about Medicaid managed care contracts comes from study of managed care contracts now being conducted by the Children's Defense Fund. Final results are expected in early 1993.

cost of serving low income children, this funding may stop unless they are under contract to managed care plans. But there is at least anecdotal evidence that some plans are failing to provide immunizations and them refusing to pay health agencies for the care they furnish to plan patients.

Ideally, managed care can lead to greater access to comprehensive care for Medicaid children. Health agencies that have spent time providing immunizations and other medical care to Medicaid patients should be able to start furnishing other services. But this evolution depends on the degree to which managed care achieves its goals. HCFA and the Public Health Service need to jointly develop performance standards for managed care that include monitoring for systematic patterns of out-of-plan care, with adjustments in the managed care contract where such problems occur and payment for out-of-plan services arising from these systematic problems.

Public Health Service programs and public vaccine supply: The Public Health Service oversees the relative handful of programs that provide subsidized immunization and health services to. low income and uninsured children and families. These programs also serve many Medicaid eligible children who face a severe primary health services. The principal programs are community and migrant health centers, the Title V Maternal and Child Health Services Block Grant, the Preventive Health Services Block Grant, the Preventive Projects Grants program, and programs offered by the Indian Health Service.

PHS-administered service programs all receive at least some of their necessary vaccine supply from state health agencies who use state and local funds (as well as funds from the Preventive Health Services Block grant) to purchase vaccine on a volume discount basis. In addition, through its Preventive Projects Program, CDC maintains bulk purchase contracts for most vaccines with vaccine manufacturers for the vaccines it purchases directly with its own funds. Both the Health Resources and Services Administration (HRSA) and the Indian Health Service are listed in the bulk contract as potential purchasers. However, the contracts appear to have an annual fixed maximum dosage amounts which are based on a CDC assumption that generally, federally administered PHS programs will receive most of the vaccines they need from state health agencies. The CDC contract does contain an "optional use clause" permitting state health agencies to purchase additional discounted vaccines. But this clause is optional with the manufacturers and can be exercised only up to the fixed purchase maximum. At least one manufacturer recently refused to sell to a state, despite no evidence that the ceiling was met and citing only broad "policy" objections to discounted purchasing.'

Theoretically the combined state and federal purchases should cover the needs of state and local health agencies, PHS-administered programs, and other community providers serving poor and uninsured children and adults. But in recent years there appears to have been a sizable growth in the number of persons in need of subsidized immunization services. Moreover, as noted, at

least some state Medicaid agencies are using free vaccine for Medicaid providers.

As a result, it appears that many state health agencies and federally funded clinics are running at least spot shortages of vaccine for uninsured patients. There also have been several instances involving state health 'agencies which, because of shortages within their own clinic system, have refused to supply health centers and IHS facilities at all on the grounds that, as federally administered programs, they should be able to receive supplies directly from the CDC. In addition, most public clinics report major shortages of Hepatitis B vaccine because of its high cost and lack of funds (a 1991 CDF study of state Medicaid vaccine programs, cited in Part Two, also found that half did not yet cover or pay for Hepatitis B vaccine).

Recent federal legislation places on CDC **direct** responsibility for assuring that community health centers have adequate supplies of vaccine. More importantly, however, the CDC, other branches of the Public Health Service, and HCFA, should develop a universal purchasing and distribution system for all publicly purchased vaccines, whether purchased with PHS-funds, Medicaid-funds or state and local funds. Ultimately this system could be extended to Medicare-covered immunizations as well.

Such a system would entail development of a single, consolidated, and enforceable bulk purchase contract with all manufacturers to cover all publicly purchased vaccines. As part of their **preventive activities, state health agencies could distribute**

their preventive activities, state health agencies could distribute supplies directly to all participating providers. In this way, publicly purchased vaccines, like publicly purchased prescribed drugs, would be secured at a uniform, discounted price and distributed in a coordinated fashion to all providers serving low income and publicly or uninsured children and adults. Moreover, in some states, Medicaid agencies actually might save money, because they are now reimbursing providers at the full retail price when they purchase vaccines to cover shortages.

WIC and AFDC: As two of the largest programs serving low income children, WIC and AFDC represent important immunization case finding points. Through co-location of WIC and immunization services, immunization monitoring and outreach at AFDC and WIC enrollment sites, and similar efforts, many children in need of immunization and ongoing primary health care might be assisted. Recent WIC and AFDC patient education and outreach activities conducted by the CDC are showing promising results. These early results should be translated into comprehensive guidance to all state AFDC, maternal and child health and WIC programs.

Office of Personnel Management: The OPM oversees a health insurance programs for federal employees which in Fiscal 1992 cost the federal government approximately $11 billion. **Yet** there are no minimum standards on immunization coverage for employee benefit plans participating in the federal government system. While OPM assumes that most of its plans do, in fact, cover vaccines, no

comprehensive review has been undertaken to assure that first dollar coverage for immediately necessary immunization services is, in fact, a well publicized feature of all plan offerings. Given the fact that many federal employees receive only modest salaries (not to mention the federal government's interest in assuring universal access to cost-saving vaccines), this review should take place as soon as possible.

TABLE 3. RECOMMENDATIONS FOR REGULATORY PROGRAMS

Program	Recommendations
ERISA	o Joint PHS/ DOL information to firms offering insured employer plans regarding recommended coverage of immunizations o PHS/DOL to gather information on extent of ERISA insured plan coverage of recommended immunizations
Internal Revenue Code	o IRS/PHS guidance to all § 501(c)(3) hospitals regarding community service immunization programs for charitable exemption purposes o IRS/PHS identify hospitals that offer community immunization programs o Joint IRS/PHS project to educate employers regarding employee benefit plan coverage of immunizations
Health Maintenance Organizations	o Joint PHS/HCFA plan for monitoring FQHMOs' provision of immunization services, including content, timeliness of appointments, and availability of fast-track programs o Joint HCFA/PHS guidance to FQHMOs on immunization coverage and practice and collaboration with national accreditation program to build specific performance standards into accreditation/quality control system

Program	Recommendations
Hill Burton	o PHS guidance to all Hill Burton facilities regarding provision of community immunization programs as uncompensated care/community service activity.

TABLE 4. RECOMMENDATIONS FOR HEALTH CARE FINANCING PROGRAMS

Program	Recommendation
Medicaid	o PHS/HCFA/Agriculture collaboration on guidance regarding combined outstationed Medicaid enrollment and fast-track immunization programs at FQHCs, DSH hospitals, WIC sites, and local health agency sites, with special emphasis placed on FQHC out-stationing sites that are also homeless health programs and migrant health centers and WIC providers o PHS/HCFA collaboration on detailed guidance to states regarding coverage of immunizations for pregnant women and children: content, vaccination schedule, recommended payment levels for immunizations and administration fees, bulk purchase arrangements for state Medicaid programs o HCFA monitoring of state payment for vaccine purchase and administration fees as part of pediatric reimbursement monitoring o HCFA/PHS collaborate on detailed standards for all Medicaid managed care plans regarding minimum required content and format of immunization programs, including fast-track services, provision of all vaccinations, and expectations regarding prompt appointments.

Program	Recommendation
Medicaid (cont.)	o HCFA and PHS collaborate on community surveillance system to monitor communities served by managed care plans to identify any sign of outbreak of disease among enrolled patients o HCFA/PHS guidance on circumstances under which FFP can be claimed for immunization programs for children who are temporarily or permanently residing under color of law. HCFA to review possibility for declaring disease outbreaks in communities a sufficient health threat to permit the immunization of children who are neither citizens nor temporary nor permanent U.S. residents under color of law. o HCFA/PHS guidance to states regarding Medicaid provider certification for all PHS funded programs furnishing immunization services and for special provider certification for Head Start and WIC programs and Title V o HCFA/PHS//ACF guidance regarding fast-track immunization services at local welfare agencies for families enrolled in AFDC, along with parent education activities funded as a Medicaid case management or outreach service. o HCFA/PHS and OHDS guidance to all child welfare agencies regarding standards for assuring a review of the immunization status of children in the child welfare system.

Program	Recommendation
Medicare	o Prompt HCFA/PHS evaluation of the influenza demonstration o HCFA/PHS guidance to all Medicare HMO providers regarding standards for provision of Medicare covered vaccines. o HCFA/ PHS review of current hepatitis B coverage rules o HCFA/PHS to assure that all PHS grantees-are enrolled as Medicare Part B suppliers at least for immunization services
Federal Employee Health Benefit Plan	o PHS/OPM monitoring of all FEHBP offerings to determine extent of childhood immunization coverage o OPM/PHS collaboration on effort to assure that all FEHBP offering include coverage of childhood immunization services

TABLE 5. RECOMMENDATIONS FOR KEY SERVICE DELIVERY PROGRAMS

Proqram	Recommendation
Community and Migrant Health Centers	o HRSA to develop bulk purchase system for C/MHCs and other directly federally administered programs, with particular attention to hepatitis B o HRSA/HCFA review of status of outstationed enrollment and all health centers and development of joint plan for implementation o Revision of C/MHC performance measures to specifically review existence of fast-track vaccination programs for children who are not regular patients

Program	Recommendation
Head Start (including Head Start Transition and Follow Through)	o PHS/OHDS/HCFA guidance on Medicaid provider certification of Head Start programs for immunization services and out-stationed Medicaid enrollment at all Head Start sites o PHS/OHDS collaboration to update all Head Start immunization guidance to the extent that it has not yet been completed o OHDS/ PHS collaboration to develop on-site vaccination services for Head Start children and siblings using Head Start nursing staff, Medicaid reimbursement and supplemental vaccine supply for non-Medicaid children. o HCFA guidance to all state Medicaid agencies regarding required relationships between Head Start and Medicaid managed care plans enrolling Head Start children, with particular emphasis on content of plans' immunization services and fast-track immunization by plans
Preventive Health Project Grants	o CDC to expand bulk purchasing activities to include all PHS programs, WIC, Medicare and Medicaid.

Program	Recommendation
Preventive Health Project Grants (cont.)	o CDC collaboration with all federal agencies conducting immunization demonstrations on both demonstration design and evaluation o Negotiate new bulk purchase contracts for all federally assisted immunization activities that also include enforceable clauses covering state health agencies that opt to purchase additional vaccines at the bulk price
Homeless Health Care and Public Housing Health Care	o Guidance to grantees regarding fast track immunization services at homeless shelters and other appropriate sites. o HRSA to assure supply of all needed vaccines

Program	Recommendation
Title V MCH Block Grant	o BMCH to develop specific program expectations regarding Title V agency implementation of statutory immunization goals for states including: o assuring sufficient public immunization services in all communities o provision of timely guidance to all child serving programs regarding the need for immunizations and where and how to obtain them o development of at least some on-site immunization capacity at all Head start agencies, WIC sites and child care centers, along with mobile services to child care centers, public housing, homeless shelters and other appropriate locations o collection and analysis of immunization data from at least all federally assisted health service programs and all providers participating in Medicaid o collaboration with state Medicaid agencies on monitoring the immunization performance of managed care programs o assistance to state Medicaid agencies in updating vaccination coverage and payment policies o collaboration with child welfare agencies to assure immunization of children within the child welfare system o assurance that at a minimum, all providers serving low income children have an adequate supply of all necessary vaccine on hand

Program	Recommendation
Preventive Health Services Block Grant	o Supplement effort of Title V agencies with additional funds for purchase of vaccines, placement of personnel, collection of data and notification of case finding programs
Indian Health Service Programs	o Develop system for monitoring immunization status of all children o Assure that all IHS funded programs have adequate supply of all vaccines o assure that all IHS funded programs fully participate in Medicaid and Medicare and offer on-site enrollment into Medicaid at least for pregnant women and children
Native Hawaiian Health	o Assure that all grantees participate in Medicare and Medicaid o assure adequate supply of vaccines and that all immunization instructions are up-to-date.

TABLE 6. CASE FINDING PROGRAMS

Program	Recommendations
Nutrition and food	o Notification of all food stamp applicants, child care food providers and child nutrition programs about availability of Medicaid for low income children and coverage of immunizations o on-site Medicaid enrollment at all WIC sites o PHS/HCFA/Agriculture collaboration to assure on-site immunization services at all WIC sites in order to avoid delayed referrals with personnel supplemented (if necessary) by personnel from other federally assisted programs PHS programs (e.g., c/mhc staff and Title V assisted staff). Medicaid reimbursement for all covered children, with supplemental vaccines for uninsured low income children
Child care	o HRSA collaboration with all HHS child care programs to assure that state and local child care agencies are assisted by state health agencies in locating a ready source of vaccine services

Program	Recommendations
Child welfare	o Collaboration with HCFA and PHS on standards for all child welfare agencies regarding immunization of children in the child welfare system and in foster care placements. Specific guidance regarding assessing child welfare cases for evidence of immunization status. o Collaboration with PHS on the development of model on-site immunization programs located in family support centers and other crisis prevention programs serving families with young children
Education	o Collaboration with PHS and HCFA to develop in-school immunization programs that are Medicaid-qualified and that use personnel from school health and PHS administered programs.
AFDC and SSI	o Social Security Administration to develop program guidance on assessing the immunization status of applicants and provision of information on immunization services.

TABLE 7. FEDERAL DEMONSTRATIONS

Recommendations
PHS to conduct a meta-evaluation of all current HHS assisted demonstrations
PHS/CDC to collaborate with all federal agencies in designing, administering and evaluating federally-assisted demonstrations involving childhood immunizations.

TABLE 8

HEALTH PROGRAM FUNDING FROM *FY* **1980** TO **1991 AND 1991** ADJUSTED FOR ACTUAL **1980** DOLLARS*

Program	80	81	82	83	84	85	86	87	88	89	90	91	91**
CHC	320	324	281	360	351	383	396	420	395	415	427	478	544
MHC	40	43	38	38	42	44	45	44	44	46	47	52	68
MCH	433	455	374	478	399	478	458	497	527	554	554	587	736
IMM	25	24	28	27	31	42	45	75	86	127	162	182	42
PBG	170	93	79	85	87	89	87	89	85	84	83	91	289

CHC=Community Health Center Block Grant
MHC=Migrant Health Center Block Grant
MCH=Maternal and Child Health Block Grant
IMM=Project Grants for Preventive Health Services (CDC)
PBG=Preventive Health and Health Services Block Grant

*figures rounded to nearest million
**1991 Figures adjusted to reflect 70% inflation rate over 1980 base rate during this time period.

Source: Edward Klebe, "Appropriations for Selected Health Programs,FY 1980-FY 1991" (Congressional Research Service, Washington, DC, October 24, 1991).

CONCLUSION

There are many health problems whose solution will elude the nation for many years. How to stop vaccine-preventable diseases is not among them. Achieving full immunization of children begins with families. But for many American' families there are sizable financial and access barriers that must be overcome if their children are to be immunized. This is where the federal government can help.

Federal agencies administering immunization programs have more than ample authority to improve and strengthen their policies and practices. Immediate steps can be taken to assure that the price of publicly purchased vaccine is uniformly low, that providers participating in public programs have a ready supply of all the vaccine they need, and that they are fairly compensated for the cost of administering immunizations. Long-term actions to make information about and access to vaccine are also within the reach of current law. And agencies that oversee programs within the private sector have a strong bargaining and public education role to play as well.

The stakes are large. Childhood poverty remains at a 20 year high. More than 35 million Americans are uninsured, while nearly 43 million Americans are medically underserved. All depend for immunizations and other essential health services on a strong federal government. Improving the performance of federal immunization programs need not await further Congressional action. The steps outlined here, like those in the Interagency Action Plan, can and must be taken now.

II. INDIVIDUAL LAWS AND PROGRAMS

A. REGULATORY PROGRAMS

1. The Employee Retirement Income Security Act (ERISA)

Sixty percent of all American children under age 18, and 70 percent of all working age adults are insured through an employer provided health insurance plan. Thus, the degree to which employer plans cover medically necessary immunizations may have a significant impact on financial access to immunization services.

Historically, the power to regulate the business of insurance -- to set standards for solvency, disclosure and content of coverage requirements and other features -- has been left to the states. Similarly, states have traditionally maintained the authority to tax insurance sales, as they would any other sales transaction or commodity. States' formal role in regulating insurance is codified in the McCarran Ferguson Act.

However, in 1974, in response to numerous problems with employer pension and benefit plans, Congress exercised its constitutional power to regulate interstate commerce and enacted the Employee Retirement Income Security Act (ERISA). In doing so, the federal government in effect "preempted" (i.e., superseded) states' power to regulate either "employee benefit pension plans or employer-provided insurance falling into the category of "employee welfare benefit plans" as defined under the Act. The preemptive powers of ERISA arise in two ways: first, a prohibition against state laws requiring the provision of coverage; and second, a preemption of state power to regulate or tax much of the health insurance that is offered by employers.

The United States Supreme Court has held that ERISA preempts states from mandating that employers provide health insurance to their employees and dependents.[1] In preempting state regulation of employer-provided health insurance, ERISA establishes two classifications of insurance: insurance purchased by employers and self-funded plans.

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[1] Standard Oil Company of California v Assalud 633 F. 2d 760 9th Cir., 1980), affirmed mem.,454 U.S. 801 (1981), holding that the Hawaii Health Care Act was preempted by ERISA. In 1982 Congress amended ERISA to provide Hawaii with an exemption from this aspect of the law. As a result, virtually all Hawaiians are insured, either through their employers of publicly.

The Court has held that while health insurance purchased by employers from private companies is still subject to state regulation under the McCarran-Ferguson Act, insurance plans that are "self-funded" (known under the Act as "insured" plans) constitute exempt "welfare" plans.[2]

Today 60 percent of all employers furnishing health insurance to their employees self insure, rather than purchase group coverage. Under a self-insured insured plan, the employer agrees to pay employees' claims as they arise rather than purchasing coverage and paying claims through premiums.[3] The value of this arrangement to employers is potentially enormous. It includes sizable savings through the avoidance of premium payments to insurance companies, state premium transaction taxes, and state laws regulating the content of purchased group insurance plans.

Thus, to the extent that group health coverage is furnished through a self-insured employer plan, state laws requiring group insurance coverage of immunizations are inapplicable. Also preempted are state taxation schemes that might tax group insurance in order to help insure non-covered persons or provide additional health services to needy populations.[4]

The avoidance of state regulation and taxation is consistent with one of the chief goals of ERISA, which was to block conflicting state laws regulating interstate employee benefits. In this way, employers could be assured of uniform national standards. However, at the time of ERISA's enactment, the emphasis was on pension plans. No minimum federal qualifying standards were set for welfare plans. The United States Department of Labor, which oversees ERISA, has not set minimum standards for the content of insured health benefit plans, nor does it maintain specific

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[2] Metropolitan Life Insurance Company v Massachusetts, 471 U.S. 224 (1985), holding that state mandated benefit laws are preempted by ERISA to the extent that they are applied to employer self-funded (i.e., employer-insured) plans. health insurance offered by employers that are not "insured" plans (i.e., that are purchased from an insurance company) are still to be treated as the business of insurance under the McCarran Ferguson Act.

[3] Employers may hire insurance companies to act as plan administrators and may purchase stop-loss or reinsurance protection. However, neither activity converts insured plans into purchased plans.

[4] It should be noted that one state -- Hawaii -- is specifically permitted under ERISA to tax and regulate self-insured plans. After the Standard Oil decision noted above was handed down, the state sought and obtained an exception from the preemption clause in 1982.

guidance for employers regarding inclusion of immunization as a benefit option.

There is no national source of information regarding the extent to which "insured" (i.e., exempt) plans cover necessary immunizations. Special studies of employer provided health insurance, however, suggest that less than half of all traditional indemnity plans cover immunizaations at all[5]; and a far lower percentage may offer coverage on a first-dollar basis (i.e., without the imposition of a deductible).[6] Employer-offered HMOs are substantially more likely to provide immunization coverage than traditional indemnity insurance. However, only about 30 million working age Americans have HMO enrollment through their employers. Thus, the majority of employer-insured children are not insured against the cost of immunizations, despite the substantial financial burdens that immunization payments can impose on families.[7]

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[5] Curtis, R., Policy Bulletin: Report on the Employer-Sponsored Health Benefit Plans Survey (HIAA, Washington, D.C., October, 1991)

[6] It is also important to underscore how many children in working families lack any employer coverage today. While over 80 percent of children live in families in which someone works, only 60 percent had employer coverage in 1990. Less than 40 percent of black and Latino children had employer coverage that year. Rosenbaum, S., et. al., Children and Health Insurance (Children's Defense Fund, Washington, D.C., 1992).

[7] National Vaccine Advisory Committee, "Access to Childhood Immunizations: Recommendations and Strategies for Action" (United States Department of Health and Human Services, April, 1992). In its April report the NVAC concluded that the cost of vaccine alone exceeded $200 for a complete immunization series for children under age 2. **This figure does not include the cost of administration, which adds significantly to the outlay.**

THE EMPLOYEE **RETIREMENT** INCOME SECURITY ACT (ERISA)

Program name and **statutory** citation	**Employee Retirement Income Security Program (ERISA), 29 USC § 1001, et. seq.**
General program structure	Regulatory statute which: (a) establishes minimum standards for employer benefit pension plans and (b) exempts employer pension and employer benefit **"welfare"** (including **self-**funded health insruance) **plans from state regulation.**
Specific authorizing provisions related to childhood immunizations	**No**
Authorized appropriations level Fiscal Year 1992	**NA**
Fiscal 1992 appropriations level	**NA**
Specific authorized funding earmark for immunizations	**NA**
Specific appropriations earmark for immunizations	**NA**
Administering agency	Department of Labor
Federal regulations	29 CFR § 2500 et. seq.
Agency guidance	No

2. Internal Revenue Code

The Internal Revenue Code is the massive body of laws that governs tax liability for individuals, corporations, and other agencies and instrumentalities. The Code specifies transactions and events that carry tax liability and those that are exempt from liability. The Code also provides for a range of deductions form income in determining tax liability.

The Code contains many provisions of potential application to immunizations. For example, the Code sets forth the conditions under which employer contributions to employee health insurance are exempt form taxation as employee compensation and may be taken as a business deduction. Certain performance requirements are built into these statutory provisions. For example, in order to deduct health insurance contributions as a business expense, employers now must offer employees continued health insurance coverage after termination of employment.[8]

Numerous health reform measures have been that would tie the deductibility of employer paid insurance premiums as a business to coverage of certain benefits. One proposal specifically would have conditioned deductibility on coverage of well-child services, including immunizations.[9] In the absence of such reform legislation, however, it is highly unlikely that the IRS could (or would) condition deductibility of minimum benefit standards. The IRS might, however, provide employers with information about the importance of immunization coverage in plans, just as it has furnished employers with extensive information about other provisions of the tax code of importance to employees, such as the earned income tax credit for low wage earners.

A more fruitful avenue for pursuit may be in the areas of tax exempt status. The federal tax code (and many state tax codes) sets standards governing when institutions are considered charitable and therefor exempt from corporate taxation. Under IRS rulings, hospitals must be organized for charitable purpose and operate to fulfill those purposes if they claim tax exempt status under Section 501 (c)(3).

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[8] 26 USC §

[9] Child Health Incentive Reform Program, S. , introduced by Senator John Chafee in 1985.

There have been state and federal law suits challenging the state and federal tax exempt charitable status of hospitals because of their failure to furnish sufficient charity care.[10]

A 1983 federal ruling broadens the grounds for charitable exemption to include hospitals that offer community health programs." Thus, community health programs are an issue in which the IRS maintains a specific interest. The IRS might, for example, notify hospitals (particularly those located in in high-risk areas) that community immunization programs constitute a charitable act for Section 501(c)(3) purposes and work with the Public Health Service to define the types of immunization programs that meet the test.

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[10] See, e.g., Lakeview Medical Center v Richardson 76 Ill. App. 3d 953 (Ct. App. 1979); Simon v Easter Kentucky Welfare Rights Organization, 426 U.S. 26 (1976).

[11] Rev. Ruling 83-157, 1983-42 IRB 9.

INTERNAL REVENUE CODE

Program name and statutory citation	26 USC §§ 1, et seq.
General program structure	Set of federal laws defining tax liability, exemptions and deductions for individuals, corporations and other agencies and instrumentalities. Exemptions and deductions frequently conditioned on certain requirements.
Specific authorizing provisions related childhood immunizations	No
Authorized appropriations level Fiscal Year 1992	NA
Fiscal 1992 appropriations level	NA
Specific authorized funding earmark for immunizations	NA
Specific appropriations earmark for immunizations	NA
Administering agency	Internal Revenue Service
Federal regulations	26 CFR §§ 1, et seq.
Agency guidance	No

3. Hill Burton Program

The Hill Burton program was enacted in 1946 as part of President Truman's national health reform proposals. The Act, known formally as the Hospital Survey and Construction Act, was created to finance the development of hospitals and other institutional health programs in areas of need. For many years no grants have been available through the program. However, all facilities receiving Hill Burton Funds are required to follow specific requirements pertaining to the provision of free care and community services.[12]

The free care provision (also known as the "reasonable volume" or "uncompensated care" requirement) obligates institutions to provide a certain amount of uncompensated care each year for 20 years following the completion of the construction or until the amount of the grant or loan is repaid.[13] The "reasonable volume" test us the lesser of either 3 percent of the facility's operating cost for the last fiscal year or 10 percent of all federal assistance received by the facility, adjusted for inflation beginning in 1979.[14] The community service obligation requires, among other things, that hospitals make their services accessible to the entire community and requires participation in Medicare and Medicaid."

In all, from 1947 to 1974 a total of $4.4 billion in grants and $2 billion loan guarantees were authorized. This means that many hospitals are still obligated to furnish uncompensated care. Moreover, hospitals that cannot demonstrate that they have met their free care obligation are required to carry over their obligations into subsequent years, effectively tolling the 20 year statute of limitations. The potential volume of free care owed by Hill Burton hospitals thus is considerable. Since community immunization programs represent one type of uncompensated service that could help satisfy hospitals' obligations under the Act, it is important to identify those hospitals that continue to have free care obligations and the extent of those obligations.

The Health Resources and Services Administration, which administers the Hill Burton free care program, could, in conjunction with the Centers for Disease Control, develop and encourage the implementation of, community immunization services initiatives as a model for Hill Burton facilities.

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12 42 USC § 291; 42 CFR § 124, Subparts F and G.

13 42 CFR § 124, Subpart F.

14 Ibid.

15 42 CFR § 124, Subpart G.

HILL BURTON

Program name and statutory citation	Hospital Construction and Survey Act (Hill Burton Act), 42 USC § 291
General program structure	Law that regulates certain service requirements for hospitals constructed with federal grants and loans made between 1947 and 1974. All facilities must provide a reasonable volume of uncompensated care and community services.
Specific authorizing provisions related to childhood immunizations.	No
Authorized appropriations level Fiscal Year 1992	None
Fiscal 1992 appropriations level	None
Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations	No
Administering agency	Health Resources and Services Administration
Federal regulations	42 CFR § 124, Subparts F and G.
Agency guidance	None specific to immunizations.

4. Health Maintenance Organization Act

The Federal Health Maintenance Organization Act, passed by Congress in 1972, authorized the establishment of health maintenance organizations and provided grants and loans for their development. The Act requires that HMOs be offered as a health insurance option to all employees working at firms of 25 persons or larger in which health insurance is offered. Currently more than 30 million Americans are enrolled in some form of managed care arrangement, although only a portion of all managed care members are enrolled with federally qualified HMOs. HMOs also enroll both Medicare and Medicaid patients.

Federal regulations establish certain minimum benefit standards that all HMOs must meet in order to maintain their federal qualification. Immunization services for children and adults are a required HMO service.[16] The Health Care Financing Administration, which administers the HMO program, has issued general guidance on service requirements under the Act. According to HCFA staff, however, there is no specific guidance governing the content or format of an HMO's childhood vaccination program. However, provision of vaccination services constitutes one of the health service activities monitored as part of quality assurance activities.

Because HMOs furnish vaccinations to millions of privately and publicly insured patients, the Act and regulations offer federal agencies a good opportunity to collaborate on a strengthened vaccination program for all sectors of the population. For example, PHS and HCFA might consider developing formal standards that not only govern the content of HMO immunization programs but set forth standards regarding "fast track" services, permissible waiting times for appointments and potential collaboration models between HMOs and other key community health providers. Examples of such collaborations would be community health education programs on immunizations and special contracts between the HMOs and local clinics and health agencies to furnish care to members' children in alternative locations (such as Head Start and day care programs). HCFA might also instruct HMOs to maintain added evening and weekend hours for immunization services for members and their families, so that appointments are easy to get.

[16] 42 CFR § 417.101(a)(8)(1991).

HEALTH MAINTENANCE ORGANIZATIONS

Program name and statutory citation	Health maintenance organizations
General program structure	Statute setting out standards for the certification of federally qualified health maintenance organizations, including minimum service requirements
Specific authorizing provisions related to childhood immunizations	Yes -- immunizations are a basic benefit. 42 USC § 300e-l(H) (i)
Authorized appropriations level Fiscal Year 1992	NA
Fiscal 1992 appropriations level.	NA
Specific authorized funding earmark for immunizations	Immunizations are part of the basic benefit package
Specific appropriations earmark for immunizations	NA
Administering agency	Health Care Financing Administration (HCFA)
Federal regulations	Yes --42 CFR § 417.100; 417.101 (a)(8)(vi)
Program guidance	General: two sections of the HMO manual issued by HCFA address immunizations -- quality assurance and delivery of services. No specific policy issuance on content of HMO vaccine program.

B. FINANCING PROGRAMS

5. Medicare

The Medicare program provides hospital and medical benefits to some 33 million Americans who are retired or severely disabled workers,[17] as well as to elderly persons who are not insured workers (such as women who have worked at home) but who elect to enroll in the program.[18] Additionally, Medicare covers all persons with end stage renal disease, including several hundred children.

The Medicare Part A program (known as HI) covers hospital, extended care, and other types of institutional services. Part B (known as supplementary medical insurance or SMI), covers physician and other medical and health care services. Among the list of covered Part B benefits are both pneumococcal and hepatitis B vaccine.[19] A federal demonstration is now under way[20] to determine the cost effectiveness of Medicare coverage of influenza vaccine. In addition, prepaid health plans participation in the Medicare program can offer enrollees benefits not normally covered under the program. Some HMOs might cover additional vaccination services in this fashion.

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[17] Medicare coverage for persons with disabilities commences no sooner than 24 months following the date on which they become entitled to SSDI benefits. 42 USC § 1395c (1992).

[18] Because these enrollees are not "insured workers", this means that they must pay premiums for Part A hospital coverage which have already been paid by insured workers through the Medicare payroll tax.

[19] Federal regulation 42 CFR § 410.63 specifies the conditions under which individuals are considered at high or intermediate risk for hepatitis B and coverage of vaccine is therefore permitted. High risk individuals are ESRD patients, clients of institutions for the mentally retarded, persons who live in the same household as a hepatitis B carrier, homosexual men, illicit injectable drug users, and Pacific Islanders other than residents of Hawaii. Intermediate risk groups are staff in institutions for the mentally retarded and classroom employees who work with the retarded, workers in health care professions who have frequent contact with blood or blood derived bodily fluids and heterosexually active persons with multiple partners. Persons are not considered at high or intermediate risk, however, if they have been screened and found to be currently positive for hepatitis B antibodies.

[20] See Section E, infra, which discusses demonstrations.

The normal Medicare Part B deductible (now $100 annually) is waived in the case of pneumococcal and influenza vaccines. It is not waived for hepatitis vaccines, however.

There is little information on Medicare coverage of and payment for vaccines. Because Medicare reimburses physicians and other providers who administer vaccines, presumably the program is paying for immunizations on a retail basis. There is no readily available information on Medicare payment for vaccine administration, although this may be an issue which has arisen as new payment methodologies for participating physicians have been developed.

Particularly important issues for the Health Care Financing Administration, which administers Medicare, would be :

- public education for beneficiaries regarding both pneumococcal and hepatitis immunizations,
- completion and analysis of research into the effectiveness and cost effectiveness of coverage of influenza vaccine;
- ongoing review of the appropriateness of current immunization coverage standards;
- the development of detailed cost and provider reimbursement information about Medicare vaccination services and how the cost to Medicare compare with the public contract price; and
- the development of specific standards for monitoring the immunization status of managed care enrollees, as well as additional information on the extent to which Medicare HMOs offer supplemental vaccination coverage as an added plan benefit.

In addition, HCFA and the Public Health Service should consider a joint collaboration to assure that all health services programs funded by PHS are participating in Medicare as immunization providers and are being adequately reimbursed for their services. In the context of Medicare support for immunization services furnished by publcily funded providers serving a high proportion of medically indigent patients, the reimbursement principles and methodologies similar to those established for federally qualified health centers[21] potentially would be appropriate.

Medicare represents the most important source of third party financing for vaccination services for the elderly. Without Medicare, many clinics may be absorbing the cost of large-scale efforts to immunize older persons against pneumococcal pneumonia and hepatitis. Working with Part B carriers, HCFA might consider establishing a fast track provider certification system for publicly funded health programs that do not normally furnish Part B services but do offer vaccination services for the elderly and for persons with disabilities.

On a longer term basis statutory issues relating to Medicare coverage of vaccines are: expanded overage for any medically necessary vaccine; and uniform principles for waiving application of the Part B deductible.

[21] Federally qualified health centers are clinics receiving funding under §§ 329 and 330 of the Public Health Service Act (community and migrant health centers). Under the Medicare statute, these clinics receive cost-based reimbursement for certain Medicare and Medicaid services.

MEDICARE

Program name and statutory citation	Medicare, 42 USC § 1395 ***et. seq.***
General program structure	Health insurance program for 33 million retired workers, disabled workers and all persons with end stage renal disease. Part A (HI) covers hospital, home health and some nursing home care. Part B (SMI) covers physician and other forms of out-patient services.
Specific authorizing provision related to childhood immunizations.	Part B benefits include pneumococcal vaccine and its administration; and hepatitis B vaccine and its administration for persons considered at high or intermediate risk, as determined by the Secretary 42 CFR § 410.63. Coverage of influenza vaccine and its administration may be added pending the outcome of federal research 42 USC § 1395x(s)(10)(A) and (B). Additional vaccines may be offered by prepaid health plans under contract to Medicare as an added benefit. The $100 annual deductible is waived for pneumococcal and influenza vaccines, but not for hepatitis vaccinations 42 USC § 13951.
Authorized appropriations level Fiscal Year 1992	Such sums as are necessary
Fiscal 1992 appropriations level	Estimated at approximately $50 billion.
Specific authorized funding earmark for immunizations	NA
Specific appropriations earmark for immunizations	NA

Administering agency	Health Care Financing Administration (HCFA)
Federal regulations	42 CFR §§ 407, 410.10, 410.12 and 410.63.
Agency guidance	No

6. Medicaid

Medicaid is by far the largest potential source of public third party financing of immunization services for children and poor adults (particularly poor women of childbearing age). Yet Medicaid has never reached its full potential in the area of immunizations. To understand why, it is necessary to consider those factors which affect the extent and quality of its performance. These are:

a. eligibility-related issues;
b. benefit/coverage issues; and
c. provider reimbursement, participation and qualification issues.

Each factor will be reviewed in turn.

A. Eligibility-Related Issues

Medicaid coverage of persons over age 18 is limited principally to women of childbearing age who are extremely poor and receiving AFDC and low income pregnant women.[22] Coverage of poor is limited to men who receive SSI benefits on the basis of a disability, members of two-parent unemployed households, and single men acting as caretaker relatives for minor children and receiving AFDC.

It is with respect to children, however, that Medicaid's role assumes enormous importance.

1. The potential reach of Medicaid eligibility

Medicaid's potential to finance childhood immunization services cannot be fully appreciated without considering the sheer magnitude of the program. As a result of increased childhood poverty during the 1980s[23] and the legislated Medicaid eligibility

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[22] All states cover pregnant women with family incomes below 133 percent of the federal poverty level. More than half cover women with family incomes between 133 and 185 percent of poverty.

[23] Between 1979 and 1989 the number of poor children increased by 2.2 million from 10.4 to 12.6 million. This growth occurred as a result of changing labor and family patterns, declining earnings, and the decreased real value of federal and state financial assistance to the poor. Johnson, C., Miranda, L., Sherman, A., and Weill, J., Child Poverty in America (Children's Defense Fund, Washington, D.C., 1991)

expansions enacted for' children over the past decade, [24]the proportion of American children either wholly or principally dependent on Medicaid has grown significantly. By 1990, nearly 12 million children under age 18 -- approximately 1 in 5 -- received Medicaid. Table 1. Without Medicaid the number of uninsured children, which in 1990 stood at 8.4 million, would have surpassed 18 million.[25]

Children under age 6, the age group most in need of immunizations, are the most likely to be poor and, consequently, the most likely to be eligible for Medicaid.

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[24] The principal expansions for children are found in the following statutes: Deficit Reduction Act of 1984, P.L. 98-369, § 2361 [adding coverage of children under age 5 with family incomes below state AFDC eligibility standards, regardless of family living arrangements]; Omnibus Budget Reconciliation Act of 1986, P.L. 99-509, § 9401 [extending to states the option to cover all pregnant woman and children under age 5 with poverty level incomes]; Omnibus Budget Reconciliation Act of 1987, P.L. 100-203 § 4101 [authorizing states to cover all infants with family incomes below 185 percent of the federal poverty level]; The Medicare Catastrophic Coverage Act of 1988, P.L. 100-360, § 302 [mandating coverage of all pregnant women and infants with family incomes at or below 100 percent of the federal poverty level and with family resources meeting state standards]; the Omnibus Budget Reconciliation Act of 1989, P.L. 101-239, § 6401 [mandating coverage of all children under age 6 with family incomes at or below 133 percent of the federal poverty level and with family resources meeting state standards]; The Omnibus Budget Reconciliation Act of 1990, P.L. 101-508, § 4601 [mandating coverage of all children born after September 30, 1983, who have attained age 6 but who have not attained age 19, with family incomes at or below 100 percent of the federal poverty level and famiiy resources meeting state standards].

[25] Rosenbaum S., Hughes D., Harris, P. and . Liu, J. Children and Health Insurance (Children's Defense Fund, Washington, D.C., 1992) p. 10. Approximately 20 percent of all Medicaid-enrolled children have some other form of insurance coverage. Adjusting for this small number of dually insured children results in an increase in the number of completely uninsured children from 8.4 million to 18.1 million in the absence of Medicaid. However, of the 20 percent of dually insured Medicaid eligible children, only a tiny fraction have a second form of coverage that includes immunizations. Most poor children with private insurance have extremely limited benefits (e.g., hospital coverage only) because of the high cost of private insurance.

In 1990, almost 25 percent of all young children were enrolled in Medicaid.[26] Moreover, expanded coverage standards for children at a time of very high childhood poverty means that in poorer states, one third of all young children, and half of all infants, now may be eligible for Medicaid.

2. Medicaid eligibility requirements and options for children

All states must extend Medicaid to four principal categories of children:

- o children receiving Aid to Families with Dependent Children (AFDC)[27];
- o children receiving Supplemental Security Income (SSI);[28]
- o "poverty level" infants and children under age 6 (family incomes up to 133% of poverty)[29]

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[26] Recent data from the Health Care Financing Administration suggest that the number may be even greater than the 1990 census data show. In September, 1992, HCFA reported that 17 million individuals under age 21were enrolled in Medicaid. This means that approximately 14 million children under age 18, and somewhere between 6 and 7 million children under age 6, were enrolled.

These numbers represent a 2 million increase over the 1990 estimates in the number of enrolled children under age 18, and perhaps a 1 million increase in the number of enrolled children under age 6.

[27] 42 USC § 1396a(a)(10)(A)(i)(1991).

[28] Ibid. SSI is the federally funded Social Security Act program for persons with disabilities. 42 USC § 1382 et. seq. (1991). It is estimated that more than a half million children, mostly very young, are eligible for SSI as a result of one or more impairments severe enough to prevent normal childhood functioning. In all states but New Hampshire, Missouri, Connecticut, Hawaii and Nebraska, children receiving SSI are automatically entitled to Medicaid. In a number of these "automatic" states, however, children must separately enroll in Medicaid in order to obtain it. In the remaining states, Medicaid coverage is sent with each monthly SSI check. Since virtually all non-institutionalized children receiving SSI are low income, the Medicaid expansions for poverty level children permit Medicaid coverage of children with disabilities even if they do not also separately qualify for SSI.

[29] Ibid.

o "poverty level" children born after September, 1983 and ages 6 to 19 (family income up to 100% of poverty)[30].

In addition, states may extend 'coverage to certain other children. The principal optional categories of children are:

o any child under age 21 who is in need of Medicaid, with financial eligibility standards and methodologies determined by the state.[31]

o infants with family incomes between 133% and 185 % of the federal poverty level[32];

o all (or reasonable sub-groupings of) children under 21 with family incomes and resources at or below AFDC financial eligibility standards[33] (a reasonable sub-grouping would be children in state-assisted foster care and adoption placements or children in medical institutions); and

o "medically needy" children with family incomes slightly higher than AFDC or SSI payment levels but inadequate to meet the cost of necessary medical care.[34]

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[30] Ibid.

[31] Section 1902(r)(2) of the Social Security Act authorizes states to set financial eligibility standards and methodologies for children (among others) that are more generous than those normally used. States are now beginning to use this option to cover most, or all, uninsured children, not just those who are uninsured and very low income. For example, Minnesota soon will begin coverage of all children under age 18 with family incomes below 275 percent of the federal poverty level. Both Texas and Rhode Island are considering similar initiatives for children under age 6. Washington State and Massachusetts also have made use of this special flexibility rule to cover additional children.

[32] 42 USC § 1396a(a)(10)(A)(ii)(1991).

[33] 42 USC § 1396a(a)(100(A)(ii)(1991).

[34] 42 USC § 1396a(a)(10)(C)(1991). Because these families must incur sizable medical expenses before their eligibility commences, the medically needy program has virtually no utility for low cost preventive services such as childhood immunizations. It is used principally to help low income individuals and families meet high cost institutional care needs, such as hospital and nursing home stays.

Table 2 shows that as of July, 1991, 28 states and the District of Columbia had elected to establish coverage standards for infants higher than the minimum 133% standard now required under federal law.

3. Enrolling in Medicaid

While children thus can qualify for Medicaid under a variety of categories, in most states, the number actually enrolled is only a small proportion of the number actually eligible.[35] This is because enrollment is so difficult, requiring completion of forms which are dozens of pages long in some instances and frequently available in no language but English. Enrollment also may require multiple visits to local welfare offices.

Amendments enacted in 1990[36] require states to provide out-stationed Medicaid enrollment programs for all poverty-level children (i.e., all poor children born after September 30, 1983 and under age 19 who are applying for Medicaid). By law, these programs must be at locations other than those used for the receipt and processing of AFDC applications (i.e., at non-welfare-office locations which must include federally qualified health centers and disproportionate share hospitals).[37] Moreover, the forms used to enroll children at these sites must be ones other than those used for AFDC.[38]

This program has great potential to find poor but non-enrolled children, if out-stationing is located at all places where poor young children come for health care -- local health agencies, WIC clinics, special immunization clinics, health centers, hospital clinics, and so forth. But while the federal statute gives two examples of mandated outstationed enrollment sites (federally qualified health centers (FQHCS)[39] and disproportionate share

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[35] Rivera, L. and Rosenbaum, S., "Untying Gordion Knots: A SO-State Survey of Implementation of the 1990 Medicaid Out-stationed Enrollment Program" (Presented at the Annual Winter Meeting of the National Association of Community Health Centers, 1992).

[36] 42 USC § 1396a(a)(55), added by § 4604 of the Omnibus Budget Reconciliation Act of 1990, cited supra.

[37] 42 USC § 1396a(a)(55)(A)(1991).

[38] Ibid.

[39] Federally qualified health centers include all federally funded community and migrant health centers and health centers for the homeless under the Stewart McKinney Act, as well as entities that meet the requirements of the community and migrant health

hospitals), HCFA guidance limits mandated out-stationed enrollment sites to these two providers alone.[40] Thus, while the federal out-stationing guidance is generally comprehensive, it permits states to satisfy the out-stationing law even if assistance is offered only at two types of provider locations. Immunization clinics, well child programs, WIC clinics and other crucial health care entry points for poor children that are neither FQHCs nor disproportionate share hospital clinics may be excluded from a state's out-stationed enrollment program.

As of December, 1991, of approximately 300 FQHCs surveyed in all fifty states and the District of Columbia, only 110 had out-stationed enrollment programs that arguably met minimum federal requirements.[41] An unknown number of hospitals had out-stationed programs. And only in a small number of states are non-mandated sites included in out-stationed programs.

4. Medicaid coverage of migrant children

One of the most vulnerable groups of children is migrant children. Deeply impoverished and exposed to a host of unique health problems and threats, these children are in particular need of good health care. By and large, their receipt of care depends on access to a small cluster of migrant health centers located along the three principal migrant streams (east, midwest and west). Because there are only slightly more than 100 such health centers, families may be forced to go weeks and months without services for their children.

The Medicaid program might offer some relief by supplying migrant children with comprehensive health insurance. But Medicaid poses particularly difficult problems for migrant children. Under federal law, migrants can elect to claim residence either in their "domicile" state (the state which they consider their permanent residence) or in any state in which they are either working or seeking employment.[42]

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centers program but do not receive federal funding. 42 USC § 1396a(l)(1991).

[40] Medical Assistance Manual, § 2905, et. seq. (Transmittal No. 71, June 1991.) The guidance does state, however, that states may, at their option, use other sites in their out-stationing programs and receive federal financial participation for the cost of programs offered at all sites.

[41] Rivera, Lourdes and Rosenbaum, Sara, Untying Gordion Knots, op. Cit.

[42] 42 CFR §435.403(i)(1991).

But this right to coverage is difficult to secure because of Medicaid's structural complexity. Their constant mobility from state to state means that by the time migrant families have applied for coverage for their children, they may be ready to move on, particularly in states in which delays in determining eligibility are lengthy.[43] Children with coverage from another state may find that no provider in the state they are living in will accept an out-of-state card even though they are entitled to care under Medicaid's out of state coverage rules.[44]

Thus although Medicaid might offer access to a broad range of primary health services, it eludes the vast majority of migrant children. A 1991 study of barriers to Medicaid eligibility, for migrant families found that the most constant reasons that children were denied coverage had to do, not with their lack of eligibility, but with their families' inability to navigate the Medicaid enrollment process.[45]

An aggressive program for migrant children might combine out-stationed enrollment into Medicaid at all migrant health centers and other strategically located sites with interstate compacts among Medicaid agencies located in key migrant stream states to assure prompt payment of out-of-state claims for primary health care.[46] To date, however, HCFA has not taken steps to assure that

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[43] By law, states have 45 days from the time an application is filed to determine eligibility. 42 CFR § 435.911(a)(2)(1991). In many states, the time period is frequently longer because of a shortage of workers.

[44] Federal regulations require states to pay for medical care furnished on an out-of-state basis if the services needed are emergencies or urgently necessary or if it is the general pattern for individuals eligible for assistance in certain areas to use services from other states. 42 CFR § 431.52(b). States must establish procedures for furnishing medical services for individuals present in the state but who are eligible for coverage under another state plan. 42 CFR § 431.52(c)(1991).

[45] National Association of Community Health Centers and Children's Defense Fund, "Barriers to Medicaid Eligibility for Patients Served by Migrant Health Centers" (NACHC, Washington, D.C., 1991).

[46] It is worth noting that legislation (H.R. 1392) introduced by Congressmen Slattery and Waxman in 1991 would grant states the authority to actually develop fully transportable Medicaid coverage for migrant children, so that enrollment in one state would automatically constitute enrollment in all states party to the agreement. In this way, coverage would always be provided on an in-state basis, thereby eliminating the need for continuous re-

all states are in compliance with the out-stationed service enrollment program, particularly at all migrant health centers and other primary health care facilities serving migrants. Nor has it developed model interstate compact programs for states to adopt to assure maximum Medicaid coverage for migrant children. Such compacts might assure that Medicaid cards for children under age 6 issued in one state are honored in all states, thereby eliminating the need for families to constantly reapply for coverage.

The compact arrangements are authorized under federal regulations governing Medicaid residency.[47]

5. Coverage of undocumented children

In many states there are considerable numbers of undocumented children who qualify for Medicaid in all respects except for their lack of lawful U.S. presence (a federal condition of eligibility). Aliens who are not residing in the U.S. "under color of law" cannot qualify for Medicaid. In these circumstances, federal law provides that otherwise eligible applicants who are undocumented may obtain coverage for emergency care only.[48] Most alien children can claim a legal presence, but regulations issued in 1990 by the Secretary of Health and Human Services are quite restrictive in their definition of what constitutes lawful status.[49]

In the context of Medicaid coverage of aliens, "emergencies" are medical conditions manifesting themselves by acute conditions of sufficient severity that the absence of immediate medical attention would place patients' health in serious jeopardy.[50] Clearly, treatment of communicable diseases in adults and children who are otherwise eligible for Medicaid but undocumented aliens would be considered "emergencies". Vaccinations probably would not be considered emergency treatment, since the service is furnished precisely to avoid the onset of an emergency medical condition. However, the statute appears to vest sufficient discretion in the Secretary to establish a less restrictive "color of law" test, at least for children, that would give lawful status to children who do not otherwise fall into the more restrictive legal alien

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enrollment or out-of-state claims payment procedures. To date, the legislation has not been considered in either the House or Senate.

[47] 42 CFR sec.431.403 et.seq. (1991).

[48] 42 USC § 1396b(v)(2)(1991).

[49] 42 CFR § 435.408 (1991). Under the rules, the INS must be specifically cognizant of the alien's residence and must affirmatively not contemplate enforcing the alien's departure.

[50] Ibid. (1991).

categories. In this way more alien children would be entitled to Medicaid for services to deter the spread of communicable disease, thereby vesting states with more financial resources to fight epidemics.

B. Benefit-Related Issues

States have the option of covering all immunization services for all beneficiaries as a preventive health service. An unknown number do so, and this should be further explored. In the case of children, however, the program's coverage requirements are far-reaching.

Medicaid entitles all enrolled persons under age 21 to a special package of comprehensive primary and preventive health benefits as part of the Early and Periodic Screening and Diagnosis and Treatment program (EPSDT). Enacted in 1967, EPSDT is a unique component of Medicaid. It is designed to assure that children with health problems are promptly screened, diagnosed and treated promptly and that they continue to receive continuous care for health problems which have been uncovered. The purpose of EPSDT is to prevent health conditions or treat them before they become significant.

Beginning with the first implementing regulations for EPSDT two decades ago[51], immunizations have been a mandatory program component. In 1989, immunizations were expressly added to the statute as a required service.[52]

As is true with all Medicaid services, states' EPSDT immunization programs must be "sufficient in amount, duration and scope to reasonably achieve their purpose".[53] Amendments to EPSDT in 1989 designed to improve and strengthen the program in a number of key respects[54], clarify that states' EPSDT service coverage rules must not merely be "reasonable" but must assure coverage for &medically necessary services, even if more restrictive coverage limitations would be reasonable and lawful in the case of adults.[55]

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[51] Although the law was enacted in 1967, no final rules were promulgated until 1971.

[52] 42 USC § 1396d(r)(1)(1991).

[53] 42 CFR § 440.230(c) (1991).

[54] A memorandum issued in January 1990, by the Children's Defense Fund health division details the 1989 EPSDT amendments. See, also, State Medicaid Manual, HCFA-Pub. 45-5 § 5350 et seq, (Transmittal No.3, April, 1990).

[55] 42 USC § 1396d(r)(5)(1991).

Immunizations are an integral part of each state's periodic EPSDT screening benefit -- that is, the regularly scheduled series of well-child exams that all infants, toddlers and children are entitled to receive under EPSDT. States' "periodicity" schedules (the schedule that determines at what age children should be periodically screened and immunized and which thus dictates Medicaid payment policies for EPSDT periodic screening services) must meet reasonable standards of medical practice.[56]

HCFA guidance on states' EPSDT immunization coverage is limited and potentially incomplete.[57] April, 1990 guidance issued after enactment of the 1989 EPSDT amendments stated that:

> States must assess whether the child has been immunized against diphtheria, pertussis, tetanus, polio, measles, rubella and mumps, and whether booster shots are needed. The child's immunization record should be available to the provider. When an updating of an immunization is medically necessary and appropriate, the state must provide it and inform the child's health supervision provider. The state must provide immunizations as recommended by the American Academy of Pediatrics (AAP) and/or local health departments.[58]

The guidance made no mention of Hepatitis B or HIB,[59] nor did it reference CDC's Advisory Committee on Immunization Practices as a standard. Moreover, while the guidance stated that necessary immunizations must be provided, it did not clarify that states have to pay health care providers furnishing periodic EPSDT immunizations on a stand-alone basis without also furnishing full EPSDT assessments.[60]

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[56] 42 USC § 1396d(r)(4)(1991).

[57] It appears that by the end of September, 1992, the agency will formally notify states that, subsequent to its April, 1990, guidance, two new immunizations -- HiB and Hepatitis B vaccine, have been added to the recommended list of childhood vaccinations and therefore should be covered as an EPSDT immunization benefit. However, as of this writing, the issuance has not been sent.

[58] Medicaid Manual, op. cit., § 5123.2(B)(April, 1990).

[59] In September, 1992, HCFA clarified that both HIB and HIV had to be covered. However, no schedules were provided.

[60] One of the most crucial changes in the 1989 amendments is mandated coverage of inter-neriodic screens--that is, assessments, immunizations, diagnosis and treatment required because someone suspects a health problem. These interperiodic EPSDT services may be furnished in-between otherwise routinely scheduled periodic EPSDT screens. 42 USC § 1396d(r)(1991). Thus, an aggressive

This policy appears to be at odds with the notion of "fast track" immunization programs, which CDC strongly recommends for particularly vulnerable populations.

Ideally, because of the crucial nature of immunizations HCFA should issue comprehensive guidance setting forth the content and structure of EPSDT immunization programs. The guidance would set forth the immunization schedule that all states must follow in order to have reasonable programs. It would also describe in detail the conditions under which immunizations must be paid for by Medicaid on either a periodic or "inter-periodic*' basis (that is, immunizations that are medically necessary and identified as needed outside of the normal screening process). The guidance would detail fast-track programs and would require coverage of such arrangements as part of a medically appropriate immunization program. It would also address in detail standards for supplemental immunization services in the case of children who are behind on their scheduled immunizations.

C. Provider Qualification, Participation, and Reimbursement

1. Provider qualification

As crucial to Medicaid as service coverage and eligibility is provider qualification standards. Assuring the quality of health care for beneficiaries is a basic requirement of all state Medicaid programs.[61] States maintain broad authority to establish reasonable qualification standards for providers of all covered services including immunizations. There is no HCFA guidance regarding qualification standards for providers of immunization services, and many state Medicaid agencies may not realize that such standards are important.

The absence of detailed provider qualification standards is especially problematic in the case of managed care plans, which now enroll nearly 10 percent of all Medicaid beneficiaries. Between 60 and 70 percent of all managed care enrollees are children. CDC has already uncovered incidents of serious quality of care problems with immunization accessibility of managed care plans in certain

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immunization program to reach all children in a neighborhood may be billed to Medicaid as an "interperiodic" EPSDT service in the event that Medicaid enrolled children are immunized, even if these children are not yet due for a periodic EPSDT exam.

Similar, immunizations upon school entry or entry into Head Start or child care may be billed as inter-periodic services.

[61] 42 USC §§ 1396a(a)(19) and (a)(30)(1991).

cities.[62] Indeed, some of the worst measles outbreaks occurred among children, the vast majority of whom were Medicaid enrolled and the great majority of whom may have been in managed care plans.

Quality of care reviews of managed care plans' pediatric services have consistently turned up significant under-immunization of children.[63]

2. Provider participation and reimbursement matters

The shortage of qualified providers willing to participate in Medicaid is legendary. In many cases, the shortage results from the absence of geographically accessible providers. In the urban and rural communities suffering from absolute provider shortages, programs such as health departments and health centers play an especially critical role. But the far more common situation, according to a recent study of medically underserved persons in the U.S.,[64] is the unwillingness of available providers to treat Medicaid beneficiaries. More than 90 percent of America's 43 million medically underserved persons live in areas which do not suffer from an absolute shortage of physicians but which have few physicians willing to treat Medicaid beneficiaries.

It is unlikely that any effort, no matter how aggressive, will eliminate the barriers to private physician services that beneficiaries face. On again-off-again eligibility, low reimbursement levels and long payment delays all contribute to the problem, and have resulted in a decline in the proportion of pediatricians willing to participate in Medicaid to a significant (or any) degree. But state efforts to reduce barriers to private physicians are important. These efforts mean raising fees and reducing other payment-related barriers.

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[62] Liu, Joe and Rosenbaum, Sara, Medicaid and Childhood Immunizations: A National Study (Children's Defense Fund, 1992) p.10.

[63] See, e.g., a 1990 review of the Dayton Area Health Plan (DAHP), a mandatory managed care system in Dayton, Ohio. Among children enrolled in Day Med, one of the participating managed care organizations, only one third were fully immunized by age two, according to a review conducted by JCAHO. DAHP has been operating with specifically granted HCFA waivers for several years, and an annual external audit is a requirement imposed by HCFA. This example makes clear that little may be done with information gleaned by these audits.

[64] Hawkins, Daniel and Rosenbaum, Sara, Lives in the Balance: A National. State and County Profile of America's Medically Underserved (National Association of Community Health Centers, Washington, D.C. 1992).

Federal law requires generally that provider payment levels be sufficient to enlist enough providers so that services under the plan are available to recipients at least to the extent that those services area available to the general population.[65] Additionally, in the case of pediatric services (defined as services furnished by a pediatrician, family practitioner, or pediatric nurse practitioner) states must submit annual documentation showing the reasonableness of their rates.[66] HCFA guidelines implementing these reporting rules (added to the statute in 1989) do not require states to provide detailed (or any) information on their immunization purchase and administration payment policies, even though administration of vaccine commonly is considered an incidental service furnished as part of a physician service.

To be considered reasonable, a state's payment for immunization services should include reimbursement for the cost of purchased vaccine and reasonable compensation for administration including recall visits when necessary. Because of the high cost of vaccines purchased through the "retail" market, however, this would prove to be a relatively expensive approach to state compliance. A preferable approach might be development of a vaccine replacement program, which would reduce provider outlay costs and potentially save state agencies money.

Under such a program, providers would not have to carry vaccine costs as an account receivable. Vaccines could be purchased through the CDC contract under a state Medicaid agency/state health agency agreement[67], thereby saving Medicaid agencies considerably by eliminating most of the need for physicians to privately purchase vaccines at "retail" prices. Savings could be invested in increasing what in many cases are extremely depressed vaccine administration fees (including fees incurred by physicians when children need a second visit to complete an immunization series).

Despite the potential of vaccine replacement programs to save Medicaid agencies money and reduce participation barriers by private physicians, and despite the general provider reimbursement requirements, a recent study of state. Medicaid immunization programs revealed that:

- only 20 states had Medicaid vaccine replacement programs;

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[65] 42 USC § 1396a(a)(30)(a); 42 CFR § 447.204(1991).

[66] 42 USC § 1396r-7(a)(1991).

[67] See the chapter on the public health service act preventive health project grants program for a further discussion of state options to establish Medicaid vaccine replacement programs.

- states with no replacement program were paying physicians far less than the cost of purchasing vaccines on a retail basis and administering them. Payment shortfalls (i.e., the difference between a physician's reasonable charge and Medicaid reimbursement levels) ranged from $40 to $60, when the reasonable charge for immunizing a 15-month-old was compared to actual state reimbursement levels. Several states maintained reimbursement levels that were actually lower than the cost of the vaccine alone.

- seventeen states refused to pay for follow-up visits in the case of children requiring a second visit to complete an immunization series.[68]

As important as reimbursement levels for private physicians are payments made to public providers, particularly health departments and health centers. Even if vaccines are furnished to these providers free of charge through the CDC contract, they incur significant administration costs. Special outreach efforts to immunize children are costly and frequently uncompensated. Moreover, many public providers run out of free vaccine and must supplement their stocks on a relatively routine basis.

All federally qualified health centers are now entitled to Medicaid reimbursement for the reasonable cost of services furnished to Medicaid beneficiaries.[69] This includes the reasonable cost of their childhood immunization programs, including the cost of purchased vaccines and the reasonable cost of vaccine administration. States may, but are not required to, reimburse health departments on a reasonable cost basis.[70] A recent study found that less than half of all surveyed states reimburse health agencies on a full reasonable cost basis.[71] Many states do not yet reimburse federally qualified health centers on a reasonable cost basis. There is no HCFA guidance that details Medicaid reimbursement requirements in the case of vaccines administered by "reasonable cost" providers.

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[68] Liu and Rosenbaum, ox). cit.

[69] 42 USC § 1396a(a)(13)(E)(1991).

[70] 42 USC § 1396a(a)(11)(1991).

[71] Association of Maternal and Child Health Programs, Full-Cost Medicaid Reimbursement for Maternal and Child Health Services: Findings from a Study of Current State Policies and Guidelines for Implementation. (Washington, D.C., 1992)

Failing to cover the reasonable costs of both types of providers forces them to use grant funds meant for serving uninsured women and children to offset Medicaid shortfalls and thereby lessens their effectiveness considerably. Moreover, there is widespread anecdotal evidence that these providers are immunizing many children ostensibly enrolled in managed care plans but not receiving immunizations through their managed care provider. There is no federal rule requiring Medicaid agencies to assure payment (either by the plans or through the general Medicaid program) in these instances. The net results of this lack of standards include (a) Medicaid payment for services never furnished by the managed care plans; (b) major revenue losses incurred by the public health system; and (c) countless under-immunized children.

3. Bulk purchase of vaccine

One means of assuring a more adequate supply of vaccines for Medicaid providers at reasonable cost is by bulk purchasing vaccines at discount prices through health departments and distributing them directly to participating providers. Providers in turn are compensated for the cost of administering vaccines. As of early 1992, as noted, however, only 20 states had such programs.[72] In other states, agencies reimbursed providers for the full retail cost of vaccines, which is considerably higher. Even more serious, there is evidence that agencies are diverting free vaccine meant for uninsured children and adults to Medicaid providers in order to 'save money. This depletes the supply of free vaccine and can cause shortfalls in programs for the uninsured.

4. Managed Care

By 1991, approximately 3 million Medicaid beneficiaries, the overwhelming majority of --- children, were enrolled in Medicaid managed care plans.[73] These numbers promise to grow, as agencies increasingly turn to managed care as a means of controlling utilization and improving patient access to care. The growth of Medicaid managed care generally tracks that for the nation's working age population (although the proportion of Medicaid beneficiaries enrolled in managed care plans is lower).

Managed care can improve access to comprehensive primary care. However, managed care can leave major access holes if contract standards and expections are incomplete or ambiguous and quality monitoring is not sufficient. At least one major measles outbreak in a large city has been traced to uninununized children in managed care plans whose contracts did not specify immunization sevices.

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[72] Liu and Rosenbaum, op. cit.

[73] National Academy for State Health Policy, Manased Care: State of the Art (Portland, Maine, 1991)

HFCA is currently involved in an initiative to test the quality of care in managed care plans. But quality of care measures affect only the services plans are under a legal obligation to provide. "There are no rules specifying sources that plans must offer. Several state managed care contracts appear to permit plans to elect to refer all children needing immunizations elsewhere. This option would appear to contradict the very heart of managed care theory, since it promotes service fragmentation and continued diversion of Medicaid children to an already over-burdened public system.

In sum, there is a pressing need for comprehensive HCFA guidance in the area of childhood immunization services that sets forth detailed coverage, provider qualification, provider reimbursement and provider participation standards for all state Medicaid programs. Of particular importance are:

- guidance to states on options for improving coverage of migrant children;

- aggressive monitoring of states' out-stationed enrollment programs, and expansion of out-stationing to all immunization sites;

- new standards that recognize disease outbreak as an "emergency" which qualifies undocumented children to Medicaid immunization coverage;

- clear, complete and accurate vaccine coverage rules that satisfy EPSDT standards;

- standards on periodic and interperiodic payment for vaccine services under the EPSDT program;

- standards for determining the reasonableness of state Medicaid payment levels for vaccines and their administration, as well as new bulk purchase vaccine replacement requirements;

- rules on payment levels for vaccine services furnished by FQHCs, local health agencies, Head Start programs and other reasonable cost health are providers for the poor;

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[74] The Children's Defense Fund and the George Washington University are currently reviewing state Medicaid managed care contracts to determine their sufficiency in delineating the plans' pediatric care responsibilities.

- specific contracting performance standards for Medicaid managed care plans, and quality assurance monitoring of plans that routinely examines both the provision of immunizations and indicators of disease outbreaks among the enrolled population.

Finally, HCFA should prepare special review materials that permit comprehensive compliance measurements of all phases of states' Medicaid immunization programs. This would better ensure program assessment of every aspect of a state program that can affect the scope and quality of its immunization coverage.

MEDICAID

Program name and statutory citation	Medicaid Title XIX of the Social Security Act; 42 USC § 1396, et. seq.
General program structure	a. Health care financing grant-in-aid program which authorizes payments to states in amounts ranging from 50 to 80 percent of their expenditures for covered medical assistance services furnished to eligible beneficiaries; b. Program entitling certain persons to payment on their behalf for covered medical assistance services. The principal categories of children entitled to Medicaid on a mandatory basis are: children receiving AFDC; children receiving SSI; children born after September 30, 1983 and under age 6, with family incomes at or below 133% of the federal poverty level and with family resources that meet state standards; and children born after September 30, 1983, who have attained age 6 but who have not yet attained age 19, whose family incomes do not exceed 100% of the federal poverty level and whose family resources do not exceed state standards. Children meeting the above eligibility standards **but not** lawfully present in the U.S. are not entitled to Medicaid coverage for servcies other than emergency care.

Specific authorizing provision related to childhood immunizations	Children: All Medicaid beneficiaries under age 21 are entitled to coverage for all medically necessary immunization services as part of the Medicaid Early and Periodic Screening Diagnosis and Treatment (EPSDT) program. 42 USC §§ 1396a(a)(10); 1396d(a)(4)(B); and 1396d(r)(1)(A)(v). Federal statutory law also sets standards for the adequacy of payment rates for childhood immunizations and governs states' authority to establish provider qualification requirements for who may furnish immunizations. Adults: preventive services, including immunizations, are an optional coverage item for persons over age 21. Status of state coverage of various vaccines for adults is unknown. Vaccines necessary for pregnant women may be a mandatory benefit.
Authorized appropriations level Fiscal Year 1992	"Such sums as are necessary."
Fiscal 1992 appropriations level	NA: estimated federal expenditure for FY 1992 is projected at $63 billion by the Congressional Budget office.
Specific authorized funding earmark for immunizations	NA: medically necessary immunizations are a specific entitlement for all persons under age 21 as part of the EPSDT program.
Specific appropriations earmark for immunizations	NA: Medicaid is an entitlement program; thus, the federal and state governments must pay for all medically necessary immunizations received by persons under age 21.

Administering agency	Health Care Financing Administration
Federal regulations	Yes. Extensive regulations, including specific regulations for the EPSDT program that require coverage of immunizations. 42 CFR § 441.56(c)(3)
Agency guidance	Yes, but limited to only certain aspects of the immunization requirement. See attached document.

7. Federal Employee Health Benefit Plan

The Federal Employee Health Benefit Program (FEHBP)[75] authorizes the provision of health insurance coverage to federal employees and their families. The program is administered by the Office of Personnel Management (OPM). An estimated 10 to 11 million individuals are insured through the 15 fee-for-service plans and 320 HMOs that participate in the program. Approximately 4 million FEHBP enrollees are federal employees; the rest are dependents. In Fiscal 1992, $10.448 billion was appropriated for the FEHBP.

Neither the statute nor the regulations specifies minimum benefits that all FEHBP plan offerings must include. Thus, as with all insurance, some FEHBP offerings may cover some or all required immunizations while others might not. Similarly, among plans covering immunizations, some may offer 100 percent coverage on a first-dollar basis (i.e., no deductibles and no coinsurance), while others might not.

It is OPM's position that it is without the statutory authority to establish by rule minimum plan offering requirements. However, the agency clearly has substantial bargaining leverage, since it has the authority to determine which plans may compete for business. OPM staff indicate that they have used this leverage to improve plan coverage to provide case management services, implement certain cost controls, and increase incentives for using PPOs. In 1991 OPM requested that all plans provide coverage in 1992 for colorectal and prostatic cancer screening. OPM also has sought adoption by plans of uniform organ transplantation rules.

When asked about why this leverage had not been used to assure coverage of all vaccinations, OPM staff indicated that they had never explored the extent to which FEHBP plans are covering immunizations. Until there is evidence of a problem, OPM staff felt that there was no reason to attempt to establish coverage as a minimum standard.

Given the breadth and complexity of the current federal immunization standards, the high out-of-pocket cost to families of insufficient coverage, the clear cost effectiveness of comprehensive vaccine coverage, and the public health dangers of inadequate vaccination status, further work between the Public Health Service and OPM is warranted. This follow up effort probably should include: a survey of all federal offerings in order to determine the current scope of immunization coverage; assuring that OPM staff have the most current vaccination coverage standards to follow as they evaluate plan offerings, and any necessary technical assistance on immunization-related issues if and when the agency negotiates plan coverage standards for vaccination services.

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[75] 5 USC § 8901 et seq. (1992).

FEDERAL EMPLOYEE HEALTH BENEFIT PROGRAM

Program name and statutory citation	Federal Employee Health Benefit Program 5 USC § 8901 *et seq.*
General program structure	Provides for health insurance coverage for about 11 million federal employees, retirees and their dependants. The program is comprised of 15 fee-for-service plans and 30 HMOs. Statute specifies that the federal government pays 70 percent of the cost of coverage
Specific authorizing provisions related to childhood immunizations	No
Authorized appropriations level Fiscal Year 1992	Such sums as may be necessary
Fiscal 1992 appropriations level	$10.448 billion (estimated federal share of coverage for enrollees and dependents)
Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations	No
Administering agency	Office of Personnel Management
Federal regulations	5 CFR § 890
Agency guidance	No

C. SERVICE DELIVERY

8. Community and Migrant Health Centers

The statutes and regulations authorizing and implementing the community and migrant health centers programs require all clinics to furnish immunizations as a required primary health service.[76] Neither the statute nor the regulations describe in detail either the content of health centers' immunization programs or the specific administrative or clinical practices and procedures that health centers are expected to follow. However, extensive and detailed federal standards for health center immunization activities can be found in interpretive guidelines issued by the Health Resources and Services Administration's Bureau of Primary Health Care (BPHC),[77] which administers both programs."

BPHC guidance on immunization practice and quality assurance can be found in several sources. These are Proaram Expectations for Community and Miarant Health Centers", the Clinical Measures Workbooks for community and migrant health centers[80] and the Primary Care Effectiveness Review."

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[76] 42 USC §§ 254b and 254c(1992); 42 CFR § 51c.102(h)(3) (1992).

[77] BPHC was formerly the Bureau of Health Care Delivery and Assistance (BCHDA). It was renamed in 1992.

[78] BPHC also administers several other programs, including the National Health Service Corps field placement program, the McKinney Homeless Health Care Program, the Native Hawaiian Health Care Program, and programs for other special underserved populations.

[79] U.S. Department of Health and Human Services, Public Health Service, HRSA/BCHDA(May, 1991).

[80] The community health centers Workbook was published in May, 1991. The migrant health centers Workbook was published in June, 1992. Different workbooks are needed because of the special health care needs of patients who are members of migrant farmworker families. For example, the extreme mobility of migrant families makes traditional measures of primary care (such as continuity of care) relatively inapplicable. The migrant Workbook is designed to address these special needs.

[81] In addition to the official agency guidance discussed here, the National Association of Community Health Centers (NACHC) developed, with funding from BPHC, a workbook entitled Accepting the Challense: Healthy Children 2000: A Primarv Care Clinical Manual for Immunization Services (National Association of Community Health Centers, Inc.) 1991. This workbook supplements the official

Taken together, these issuances represent the most comprehensive immunization guidance on for any federally funded health program -- a notable fact considering the very modest size of the health centers programs compared to other programs (such as Medicaid).

In its Proaram Exnectations guidance, BCHDA states that all health centers should practice in a clinical style that encourages rapid access to immunization services. Specifically, the guidance states that:

> "Patient flow and appointment systems should foster continuity of care and minimize both appointment and office waiting time as well as "no shows". Patient flow and appointment systems should also provide triage for emergent health problems, walk in patients, and other special health problems such as immunizations, pregnancy tests and so forth. " [emphasis added][82]

The guidance also places priority on the use of comprehensive clinical information systems, including the Problem Oriented Medical Record, and recall systems for routine preventive services and patient tracking.[83] Finally the Guidance requires all health centers to have ongoing quality assurance programs that monitor clinical performance consistent with the Year 2000 Goals.

For each indicator a set of clinical performance measures has been developed. The Bureau's Clinical Measures Workbook sets out a detailed format for reviewing the quality of care furnished by health centers. The Workbook is designed to focus on "critical primary care interventions throughout all five life cycles."[84] All health centers, beginning in Fiscal 1993, are required to use the indicator measures to establish a baseline for each outcome. Through a process of negotiation with the Public Health Service, each measure is then assigned a 3-to-5 year annual incremental improvement objective against which the center's performance will be assessed.

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agency guidance with further information on the provision of immunization services.

[82] Program Exnectations, op. cit. at p.20.

[83] Ibid., p. 21.

[84] Ibid., p. 22. These life cycles are infancy, childhood, adolescence, adulthood, and old age.

According to BPHC, these goals (and centers' progress toward them), will not be used to make funding decisions." Instead they will be used as a self assessment quality assurance device and planning tool as well as for program operation purposes. However, data obtained from centers part of the clinical measures process must be included as part of their tri-annual comprehensive grant applications, as well as their annual project renewal grant applications. These data will be incorporated into BCHDANET, the Bureau's comprehensive computerized data system for health center, National Health Service Corps, and other program-related information.[86]

In the case of immunizations the following clinical measure is used:

> "A child immunized on schedule has received immunizations following the schedule recommended by the American Academy of Pediatrics (AAP) or the CDC's Immunization Practices Advisory Committee (ACIP). This includes DTP, OPV, MMR and HIB vaccines given according to the standard schedule for children who start immunizations at age 2 months, or the AAP modified schedule for children who start immunizations later."[87]

The Workbook states that:

> "The chart is defined as in compliance when all appropriate immunizations have been entered and include both the month and year the vaccines were given."[88]

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[85] Workbook, op. cit., p. 5.

[86] Conversation with BCHDA officials, March 20, 1992.

[87] Workbook, on. cit. at p. 14. Presumably this workbook will be updated to reflect the addition of Hepatitis B as a required immunization.

[88] Workbook, on. cit. at p. 15. The chart review does not appear to specifically monitor for patient informing under the National Vaccine Injury Compensation Act. However, NACHC's publication, Accepting the Challenge, makes clear that informing in accordance with the Act constitutes an essential part of vaccine practice, along with patient tracking. Accenting the Challenge, op. cit. at pp. 19-20.

The Workbook protocol requires a review of at least 25 charts of children ages 18-24 months at the time of the review. In the case of non-migrant children, charts reviewed are to include children:

- who have made 3 or more visits to the health center; and
- whose visits have occurred over a period of three months or more.[89]

In the case of miarant children, the charts to be reviewed must include children who had at least one well child visit (in recognition of the lack of continuity of care for members of farmworker families). Additionally, the migrant Workbook expressly emphasizes simultaneous vaccination with multiple vaccines and the use of routine vaccination of children with minor illnesses.[90] This emphasis on quality review measures that include simultaneous immunization and immunization in the presence of minor illness is meant to underscore the need to maximize immunization efforts whenever contact with a migrant child is made.

In addition to the chart reviews required by the Workbook guidelines, BPHC has also instituted a Primary Care Effectiveness Review system. This system, required for all centers, is designed to assure that health centers function in ways that promote the effective provision of primary health services. Key elements of the review include assessment of health centers' evening and weekend sessions, triage of walk-in patients, patient follow-up, medical records that document the provision of immunization services, and other appropriate primary care practices.

In addition to setting standards for clinical performance, the Bureau of Health Care Delivery Assistance also oversees other aspects of health center operations. One important function is assuring that all grantees have adequate supplies of vaccines. While health centers in most states are able to secure reasonably adequate supplies of free vaccine from their state health agencies, a recent study documented that over 70 percent are running spot

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[89] Workbook, on. cit. at p. 15. The review for non-migrant children thus emphasizes monitoring performance in the case of children who are relatively continuous patients of the health center. While the performance expectations guidance discusses the need for immunization of walk-in children, the quality of care review process does not specifically monitor health center performance in this important area.

[90] Migrant Workbook op. cit., at p. 10.

(and sometimes significant) shortages of vaccine.[91] Particularly severe shortages have been reported in the case of Hepatitis B vaccine, which is in short supply to state health agencies generally.= Moreover, there has been at least one documented instance of a state health officer refusing to supply health centers with any CDC vaccine.[93] Health centers' funding levels are too low to permit them to purchase vaccines at the retail price,[94] which can be three to four times the CDC contract price.

BCHDA's parent agency, the Health Resources Services Administration (HRSA), plays an important role in working with CDC to ensure an adequate supply of free or low cost vaccine. With 25 percent of the more than 6 million health center patients being children under age 6 (virtually all of whom are low income), a

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[91] Rosenbaum, S., Immunization Barriers Faced by Community and Misrant Health Centers and their Patients (Children's Defense Fund, 1991).

[92] For example, the BPHC reports that while health centers in Region IV are receiving DTP, TOPV, MMR, Td and Hib free of charge from health departments, no states supply Hepatitis b vaccine to health centers for all infants and no state permits health centers to buy additional supplies of vaccine through the health department at the federal contract price.

[93] See study chapter on the preventive health services grant program.

[94] In the case of Medicaid insured health center patients, Medicaid should pay the reasonable cost of all vaccines they purchase, as well as the reasonable cost of administering the vaccine. This reasonable cost reimbursement methodology was mandated by Congress in 1989 as part of the Federally Qualified Health Centers amendment contained in the Omnibus Budget Reconciliation Act of 1989. See, Rosenbaum, S. " A Review of Selected Medicaid Reforms Enacted During the 1980s" Presented at the July 21, 1992, meeting of the Kaiser Commission on the Future of Medicaid. However, half of all health center patients are either complete uninsured. Many more are inadequately insured against the cost of immunization. For example, patients enrolled in Medicare are entitled to pneumococcal and hepatitis b vaccine benefits, and health centers are paid the reasonable cost for this service. But other vaccines are not covered under Medicare. Similarly, while Medicaid children under 21 are covered for all medically necessary vaccines, state coverage rules for adults vary dramatically. For these patients, centers must either be able to obtain free vaccines (and absorb the cost of administration within their grants) or else have access to vaccine at an extremely low price.

steady supply of vaccine for all HRSA-funded programs [95] is absolutely essential. The CDC has, in fact, included HRSA in its federal purchase contract. HRSA's inclusion in the federal contract means that the agency can secure for health centers (and other HRSA programs for underserved Americans) a supplemental supply of low cost vaccine in the event that their free supplies run out.

Recent legislation enacted by Congress expands the responsibility of the Centers for Disease control to directly assure that health centers have adequate supplies of all vaccine.[96] HRSA and CDC have begun efforts to carry out this important change in the law. In addition, a current HRSA/CDC Hepatitis b demonstration is expected to make a modest improvement in immunization rates among health center patients against this disease.[97]

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[95] HRSA oversees a number of programs described in this compendium. See, e.g., the programs reviewed in the health services section.

[96] P.L. 102-531(1992)

[97] The demonstration is under way at 7 health center sites (there are currently approximately 600 health centers with locations in more than 2000 sites). At these demonstration sites the following patients are being targeted: infants born to pregnant Hepatitis positive women who have been identified through first trimester screening, universal immunization of infants, high risk adolescents, and sexual contacts of Hepatitis-positive adults. See, generally, Prosress Report: Action Plan to Improve Access to Immunization Services (Interagency Committee on Immunization, September, 1992).

COMMUNITY AND MIGRANT HEALTH CENTERS

Program name and statutory citation	Community Health Centers 42 USC § 254c	Migrant Health Centers 42 USC § 254b
General program structure	Federally administered program grants to furnish health services to medically underserved areas and populations. (Note: In defining MUAs and MUPs the Secretary is required to take into account "factors indicative of the health status of a population or service area. Immunization status not specifically identified as a health measure)	Same, but high migrant impact areas are also identified (> 4000 migrant or seasonal farmworkers annually).
Specific authorizing provision related to childhood immunizations	By implication. Primary health services include "preventive" and "well child" services	Same
Authorized appropriation level Fiscal Year 1992	Such sums	Such sums
Fiscal 1992 appropriations level	$527 million	$57.7 million
Specific authorized funding earmark for immunizations	None	None

Specific appropriations earmark for immunizations	None	None
Administering agency	Health Resources and Services Administration, USPHS	Same
Federal regulations	Yes. 42 CFR Part 51c.102(h)(3) specifically identifies immunizations as a primary (required) preventive health service for all grantees.	Yes. 42 CFR Part 56.102(l)(3)
Agency guidance	Yes	Same

9. Title V Maternal and Child Health Services Block Grant

The MCH block grant program provides formula grants to states for the purpose of improving the health of all mothers and children (particularly low-income families or those with limited access to health care), in accordance with national health objectives established under the Public Health Service Act for the Year 2000 (Healthy People 2000).[98] The program, initiated by Congress in 1935, is administered within HHS by the Maternal and Child Health Bureau (MCHB), Health Resources and Services Administration (HRSA).

The overall goal of the MCH block grant program is to improve the health status of mothers and children through direct services provided by or paid for by state and local governments. There are three primary Title V program components: (1) preventive and primary care services for pregnant women, mothers and infants up to age one; (2) preventive and primary care services for children and adolescents; and (3) services for children with special health care needs and their families.

In 1981, Congress consolidated categorical maternal and child health services programs into the block grant format, a move that has been criticized as undermining the development of national standards for maternal and child health.[99] Although this legislation required states to expend MCH block funds on specific maternal and child health goals, states did not have to allot MCH funds to any particular services.[100]

The MCH block grant program was amended in 1989 in an effort to improve state planning, accountability, and administration of MCH programs, to target funds to priority populations, and to link the objectives of the program to those set out in Healthy People

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[98] See Public Health Service. Health People 2000: National Health Promotion and Disease Prevention Objectives. Washington, DC. U.S. Department of Health and Human Services, 1990. Specific health objectives for maternal and child health in Healthy People 2000 include increasing to at least 90 percent the proportion of children under age 2 who complete the basic immunization series.

[99] The Budget Omnibus Reconciliation Act of 1981, Pub. L. No. 97-35. Schlesinger, M.J. and Eisenberg, L. (Eds.) (1991). Children in a Changing Health System: Assessments and Proposals for Reform. Baltimore, MD: The Johns Hopkins University Press.

[100] The statute requires that states use at least 30 percent of funds for preventive and primary care services for children. 42 USC § 705(a)(3)(A). The statute also requires that states establish a "fair method for allocating funds" to MCH programs. 42 USC § 705(a)(5)(A).

2000.[101] The 1989 amendments attempted to reduce the discretion of states to allot MCH funds by requiring states to earmark'at least 30% of the MCH funds for provision of preventive and primary care services to children and 30% for children with special health care needs.[102] The goals of the program were also revised to expressly state that one of the purposes of MCH funding is to "increase the number of children (especially preschool children) appropriately immunized against disease."[103]

These amendments also establish a new application and reporting process for the states, and mandate outreach activities. For example, state agencies receiving MCH funds must now meet annual reporting requirements that include descriptions of the types of MCH activities carried out by the state, the types of services provided and the amounts spent on these activities and services, progress toward Healthy People 2000 objectives, and a number of maternal and child health status indicators.[104] Specific. reporting requirements include information (by county racial and ethnic group) on the proportion of children, who at their second birthday, have been vaccinated against measles, mumps, rubella, polio, diphtheria, tetanus, pertussis, Hib meningitis, and hepatitis B.[105]

Although the overall MCH program goals and targeting of specific populations of low-income pregnant women, mothers, and children are laudable, the absence of any program regulations[106] and lack of concrete agency guidance on how MCH block grant funds could be used most effectively to achieve statutory goals significantly impedes the agency's ability to promote immunizations at the state and local level. The agency has stated it has no immediate plans to issue any regulations for the MCH program.[107]

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[101] Pub. L. No. 101-239, Title VI, § 6501(a), 103 Stat. 2273.

[102] 42 U.S.C. § 705(a) (3) (A), (B)(1992).

[103] 42 U.S.C. § 701(a)(1)(B)(1992).

[104] 42 U.S.C. § 706(1992).

[105] Ibid.

[106] The only regulations for the MCH program are those that govern all of Title 42 block grant programs at 45 CFR 96.1 et seq. These regulations address grant application and fiscal management. They provide no substantive program guidance for grantees.

[107] 1992 grant guidance, Appendix E: Qs and As, p. 2.

The most recent agency guidance manual (draft) for 1992 MCH block grant applicants acknowledges that under the 1989 MCH statutory amendments States must commit: (1) "to assuming a critical role in facilitating enrollment in the State's Medicaid program for large numbers of newly-eligible pregnant women and young children"; (2) "for assuring access to needed Title V-Medicaid provider information and services"; and (3) "for acting as a focal point for effectively.coordinatingthe resources of related Federal programs and agencies services mothers and children .. ".[108] Nevertheless, there is virtually nothing in the 1992 guidance manual that specifically addresses how States should go about implementing these critically important statutory goals.

There is no emphasis in the agency guidance upon immunization, especially for children under 2, the population specifically targeted by the 1989 MCH amendments and Healthy People 2000[109]. Furthermore, where the agency defines essential MCH program terms such as "primary care"[110] and "preventive services,"[111] there is no specific inclusion of immunizations under either term. The grant guidance does, however, discuss services that "should" be included in preventive and primary care services for pregnant women, infants and children and specifies "immunization" among several other

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[108] 1992 MCH Block Grant Guidance, p. 1.

[109] With regard to the Healthy People 2000 objectives, agency guidance says that all states "are expected to use all National MCH Objectives by either adopting them or adapting them." There is no explanation of how states might "adapt" these objectives. 1992 MCH Block Grant Guidance, p. 4.

[110] The term "primary care" is defined in the 1992 MCH Block Grant Guidance, p. 79, as follows:

> [T]he provision of comprehensive personal health services that include health maintenance and preventive services, initial assessment ofhealth problems, treatment of uncomplicated and diagnosed chronic health problems, and the overall management of an individuals's of family's health care services. Furthermore, it is the initial contact for personal health services and provides for continuity of services and indicated referral for and overall management responsibility of secondary and tertiary care.

[111] The 1992 MCH Block Grant Guidance, p. 80, defines "preventive care" as follows:

> [A]ctivities aimed at reducing the incidence of health problems, reducing the prevalence of community and personal risk factors for illness. When provided on a personal level, these activities should be part of an overall primary care program.

possible services and needs assessments.[112] There is no mention of the CDC protocol for immunizations. None of the services included within preventive and primary care is deemed essential or as constituting a minimum level of care that must be provided to eligible populations. There is no effort to stress the importance of immunizations or otherwise sensitize states to immunization needs.[113]

The agency guidance does not set forth uniform methods for conducting state MCH needs assessments, other than requiring states to include data elements required for annual reporting requirements. There is no uniform methodology required to develop state service plans to address these MCH needs or to analyze needs data obtained by states.[114] With regard to monitoring quality of care provided to MCH clients and overall program surveillance, the guidance simply requires states to describe their program monitoring processesand quality assurance procedures but does not specify any process components or care standards. The guidance requires MCH staff to collaborate and coordinate with Medicaid (and other program offices (e.g. WIC and family planning), but does not specific any procedures for doing so. The guidance points out that MCH staff are required to identify Medicaid eligible clients and assist them in applying for coverage but does not specify the extent of this assistance and whether MCH staff must be knowledgeable about Medicaid coverage standards.

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[112] Agency Guidance, supra, n. 1 at p. 9 and 10. This appears to be the only reference to immunizations in the entire agency manual.

[113] For example, the guidance might address the possibility of a structuring a relationship between the MCH program and funds received under the Preventive Health and-Health Services Block Grant program, 42 USC 300w, and the Project Grants for Preventive Health Services, 42 USC 247b, where funds could be used together to support personnel and service delivery costs such as vaccine purchase.

[114] The guidance refers applicants to methodologies described in Klerman, Russell, and Valadian, Promotins the Health of Women and Children Throush Planning, 1982; and Klerman and Rosenback, Needs Indicators in Matiernal and Child Health Planning, 1984.

The major challenges facing the program lie in three key areas. First is coordination of state immunization activities for children in child serving programs. The Bureau of Maternal and Child Health and other key federal agencies should collaborate on comprehensive guidance to state agencies that identifies key programs and describes activities designed to keep these programs abreast of changes in immunization standards and Medicaid coverage rules and where and how assistance can be obtained for families.

Second is collaboration with state Medicaid programs on immunization coverage, payment level and monitoring activities. Title V agencies can be of immense assistance to Medicaid agencies in the design of their immunization programs, the development of provider certification standards (particularly in the case of managed care plans) and in activities designed to assure that children receive the services to which they are entitled (both through Title V assisted clinics and the providers). Bureau guidance, issued jointly with HCFA, on the Title V/Title XIX relationship, would be extremely helpful.

Finally, Title V agencies have a critical role to play in data collection. At a minimum, all Title V agencies should be collecting data from immunization records of all publicly-assisted maternal and child health providers. Ideally, this uniform data collection system should extend to all children.

MATERNAL AND CHILD HEALTH SERVICES BLOCK GRANT

Program name and statutory citation	Maternal and child health services 42 USC § 701-709
General program structure	Grants to states to provide quality, comprehensive health services to mothers and their children; grants/contracts to fund research, training counseling, education and dissemination projects.
Specific authorizing provision related to childhood immunizations	Statutory goals include increasing "the number of children (especially pre-school children) appropriately immunized."
Authorized appropriations level Fiscal Year 1992	$686 million
Fiscal 1992 appropriations level	$650 million
Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations	No
Administering agency	HHS/HRSA
Federal regulations	45 CFR 96
Agency guidance	Yes, 1992 MCH Block Grant Guidance (Draft)

10. Project Grants for Preventive Health Services

From a statutory point of view, perhaps the most notable aspect of the preventive health project program[115] is the spareness of the law.[116] The statute vests extremely broad discretion in the Secretary to make grants to states, local governments and other public entities "to assist them in meeting the costs of establishing and maintaining preventive health service programs."[117] Indeed, on its face, the statute does not compel states to offer any immunization services as part of their preventive health services programs.[118] The statute also authorizes the Secretary to make grants to states, public subdivisions and non-profit entities for vaccine and preventable disease research, demonstration and control activities."[119]

Like many Public Health Service Act laws, the statute thus vests broad discretion in the Secretary to establish minimum standards for the content, structure and scope of state preventive health service programs. The Centers for Disease Control, which administers the program, has promulgated both regulations and guidelines regarding state immunization programs funded under the Act.

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[115] Section 317 of the Public Health Service Act, 42 USC § 247b (1991).

[116] While the authorizing legislation is spare, annual appropriations bills frequently specify in considerable detail the types of immunization-related activities which the Secretary must undertake.

[117] 42 USC § 247b(a)(1991).

[118] This is not to suggest that states have sought preventive health grants that do not include vaccine services. It is interesting, however, that the nation's largest grant program for supplying low cost vaccines and vaccine support activities to state health agencies does not mention the word at all, nor does it require minimum vaccine-related activities.

[119] 42 USC § 247b(k)(1991).

CDC Regulations and Guidance

Regulations implementing the statute specify minimum requirements for state childhood immunization programs funded under the Act.[120] Applications must:

- address need and immediate and long-range objectives and must identify "current immunization programs" and the additional activities to be carried out to meet the need;
- include a plan to assure that children begin and complete their immunizations on schedule;[121]
- include use of a "standard immunization record card"[122], a public and private "provider based tickler system",[123] and a hospital based immunization education program for new mothers;[124]
- assess the immunization status of children entering school, day care centers, children under 2 years of age and new public clinic patients under age 5;[125]
- include a plan for vaccine-preventable disease surveillance and reporting,[126] and procedures for prompt review of morbidity surveillance data to permit the prompt reporting of measles, polio and diphtheria cases;[127] and

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[120] The regulations defines a state childhood immunization program as "a preventive health services program to immunize children against vaccine preventable diseases including poliomyelitis, measles, mumps, rubella, diphtheria, pertussis and tetanus. 42 CFR § 51b.202(1991). The rule apparently has not been updated to specifically include HIB or hepatitis B.

[121] 42 CFR § 51b.204(a)(4)(i)(1991).

[122] Ibid.

[123] Ibid.

[124] Ibid.

[125] 42 CFR § 51b.204(a)(4)(ii)(1991).

[126] 42 CFR § 51b.204(a)(4)(iii) and (v)(1991).

[127] 42 CFR § 51b.204(a)(4)(iv)(1991).

- include systems for monitoring adverse reactions to vaccines and for Wigorously enforcing" school immunization laws.'**

The rules are silent with respect to the actual design of state programs. However, in evaluating state applications, the Secretary is required to take into account, among other things:

- the extent to which the proposed program will increase the immunization rates in the populations identified (in the state plan) as having the lowest immunization levels[129]; and
- the extent to which the grantee will cooperate with and use public and private nonprofit entities and volunteers.[130]

CDC guidance provides somewhat more extensive detail on state program requirements. Broad program goals for all vaccine preventable diseases are set out for both children and adults, covering all categories of disease.[131] The guidance makes clear that state programs must be "integrated and comprehensive" and that special attention is to be paid to economically disadvantaged and medically underserved infants and children.[132] Applications must include both vaccine inventories and projections of the number of dosages to be used during the budget period.[133]

All applications must include specific program objectives which are "realistic, time-limited, measurable and outcome-oriented."[134] Objectives must be both short-term and long-term and must include specific sub-population objectives.

As with the rules, however, the guidance sets forth only extremely broad minimum requirements for state programs. For example, while all plans must assess the vaccine status of populations thought to have low levels of immunization[135], no specific sub-populations are identified in the guidance for

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128 42 CFR § 51b.204(a)(v) and (vi) (1991).

129 42 CFR § 51b.205(b)(3)(1991).

130 42 CFR § 51b.205(b)(4)(1991).

131 CDC, 1992 Immunization Program Guidance at page 1.

132 Ibid,

133 Ibid., page 2.

134 Ibid., p.2.

135 Ibid., page 3.

required assessment. Examples are given (e.g., "such as inner cities", "such as WIC participants", "such as minority children")[136] However, no specific population assessments must be made (e.g., cities with a population density or poverty level exceeding certain minimum thresholds, Native American or recent immigrant children).

Similarly, the guidance requires a description of "collaborative efforts" with a range of programs including the Medicaid Early and Periodic Screening, Diagnosis and Treatment program (EPSDT), Aid to Families with Dependent Children (AFDC), community and migrant health centers, Indian Health Service facilities, health maintenance organizations, "community based organizations", and other entities.[137] It is not clear what such "collaborative efforts" entail.

In the context of the program, it would seem that collaboration would, at a minimum, include supplying vaccine and technical and administrative support to these complementary programs that serve thousands of low income children (e.g., vaccine distributed to all EPSDT and WIC providers and health centers, training of personnel employed at these facilities and programs). However, the term "collaboration" is extremely broad. It does not require state grantees to do careful assessment of the immunization capabilities of key health providers in high need areas, nor does it require states to commit any resources to these providers if their own funds prove insufficient. Nor is the state agency required to train or give technical support to these providers.[138]

To address the high cost of vaccines, the CDC guidance also recommends but does not require state health agencies to enter into vaccine replacement program agreements with state medicaid agencies that utilize the specially discounted process availablethroughthe

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[136] Ibid. page 3.

[137] Ibid., 3 .

[138] In its draft 1992 Immunization Action Plan (IAP) Program Guidance, the CDC prohibits state and local health agency grantees from using IAP grants to aid organizations receiving "direct funding from other federal sources for activities which include immunizations". Guidance, p. 9. This provision appears not only to be at odds with CDC's general collaboration directives but renders nearly impossible grants to any health organization receiving federal funding for activities that include immunizations. Examples of such programs include WIC agencies, public housing health programs, Indian Health Service facilities, migrant and community health centers, Title V-assisted health agencies, and so forth.

CDC federal vaccine contracts (discussed below).[139] The guidance also "encourages" grantees to supply vaccines to community and migrant health centers and to Indian Health Service facilities.[140] However, the guidance does not require that state agencies supply vaccine, administrative and technical support to all (or at least to certain specified) publicly funded health programs for poor and underserved children and adults. [141] Nor does it require grantees to give such programs access through the CDC federal contract (which also covers state health agencies, as discussed below) to obtain supplemental vaccine supplies at the contract price in the event that their free supplies prove inadequate.

Data on the incidence of vaccine preventable disease and age-specific information must be reported, and states must maintain vaccine administration information by antigen, dose and age group.[142] However, reviews of the immunization status of key subgroups of children and adults fall into the "recommendation" category.

The CDC Federal Contract Program

In addition to overseeing the state grants program through regulations and guidance, the CDC negotiates annual contracts with vaccine manufacturers to secure a supply of low cost vaccine for state health agencies participating in the grants program.

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[139] Ibid., 3 .

[140] Ibid., p.3.

[141] Indeed, in recent months the Alabama state health agency attempted to completely curtail provision of free vaccine to federally funded community health centers (see attached article from the APHCA Newsletter). Such complete elimination of the program would have cost the state's health centers between $500,000 and $600,000 (the amount needed to buy vaccine directly from manufacturers). Current estimates place the number of medically undeserved persons in Alabama at 1.1 million, with 65 of 67 counties medically undeserved. Currently only slightly more than 20 percent of the states undeserved persons have access to health centers because of the shortage of funds for centers. Hawkins, Daniel and Rosenbaum, Sara, Lives in the Balance: A National. State and County Profile of America's Medically Underserved (National Association of Community Health Centers, 1992). In the report, medically underserved persons have incomes below 200 percent of the federal poverty level and are either completely uninsured or publicly insured.

[142] Ibid., p. 10.

A review of the federal immunization program is not complete without an assessment of this all -important federal contracts activity, because it is these contracts that make vaccines financially accessible to the public sector.

All vaccine purchased with § 317 program funds is covered by the contract system. We examined a representative contract between CDC and Merck Sharp and Dohme for the purchase of MMR vaccine.[143] In addition to the basic agreement between CDC and Merck, the contract contains a clause permitting state health agencies and the Health Resources and Services Administration (HRSA) to obtain additional supplies of vaccine (beyond those purchased with vaccine program funds) at the federal contract price.[144] This clause is known as an '@optional use" clause.[145]

Upon closer examination, however, it appears that as currently drafted, the optional use clause has three potential problems. First, on its face the clause is limited in scope to certain federal agencies and programs. Thus, the clause does not assure that other federally administered health programs, such as family planning and Head Start have access to a sufficient supply of low cost vaccine. These programs remain dependent on state health departments which frequently may not have sufficient supplies of their own.

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[143] Award-Contract 200-91-0053, covering the one year period commencing February 27, 1991.

[144] Legislation (S. 493), which passed in the Senate in 1991 and is now awaiting House/Senate conference, would amend the statute to require the Department to develop bulk purchasing programs for both state health agencies and community and migrant health centers and health programs for the homeless. The legislation would establish a minimum amount to be spent by the CDC on bulk purchased vaccines and would require state health agencies to make such publicly purchased vaccines available to health centers and homeless projects. Consideration is also being given to broaden the CDC federal contract program to reach all federally assisted health care programs.

[145] See, e.g., Merck, Sharp and Dohme contract, § H.4.(c),pg.17

The contract may place limitations on the purchase 'of bulk vaccine that are too restrictive given the current level of need among both federal agencies and state health agencies. The contracts place both annual and monthly upper limits on the amount of antigens that can be purchased **at** the contract price and further specifies that all purchases by CDC, HRSA, and state and local health agencies count toward this annual and monthly **maximum.**[146]

Third, while the contract allows state and local health agencies to place orders against the amounts specified in the contract using additional state, local or federal funds, the contract specifies merely that " the Contractor is encouraged to honor orders from these agencies. " In other words, the manufacturer is not bound to honor the optional use clause. Indeed, the attached letter from Lederle Laboratory dated January 31, 1992, suggests an unwillingness on the part of at least certain manufacturers to meet the growing demand 'for low cost vaccine in certain states.

Given the need for a plentiful supply of reduced price vaccine for all private sector programs, the scope of the CDC contract, and the agencies covered by the contract, should be reevaluated. Both HRSA and the Indian Health Service could arrange to have CDC purchase and deliver to all grantees. At the same time, consideration should be given to including both HCFA and the state Medicaid programs in the contract in order to assure the lowest possible vaccine prices for Medicare and Medicaid beneficiaries.

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[146] Merck, Sharp and Dohme contract Sec. B.l. The contract specifies annual and monthly vaccine maximums, as well as minimum guarantees for MMR dosages and further specifies (sec. H.11, p.20) that orders placed by HRSA and state and local health agencies count toward the minimum guarantee. Similarly, the maximum dosage limitations appear to apply to all purchasers. (Sec.H. 10, pp.19-20). Thus, were all states health agencies to follow CDC recommendations and implement Medicaid replacement programs or furnish vaccines for all publicly funded health programs serving the poor, it is unclear whether the maximum ceilings contained in the contract would accommodate the orders.

In this regard, a clear precedent for discounted pricing of vaccines to HCFA-administered programs are the 1990 Medicaid amendments which established a rebate system for Medicaid-purchased drugs[147] and which is now in the process of being expanded. The 1992 extension of this mandated drug discouting to PHS programs strengthens the precedent.[148] Finally, the CDC contract should be extended to Head Start programs and other PHS programs as well. This would leave state health agencies in a stronger position to buy for other sites such as local health departments.

[147] § 9741, P.L. 101-508, the Omnibus Budget Reconciliation Act of 1990.

[148] H.R. 5193 (102d Congress)

PROJECT GRANTS FOR PREVENTIVE HEALTH SERVICES

Program name and statutory citation	Project grants for preventive health services 42 USC § 247b
General program structure	a. Grants to states or political subdivisions or other public entities to assist them in meeting the costs of establishing and maintaining preventive health services; b. Grants to states, political subdivisions and other public and non-profit entities for research, demonstration, public information and education and clinical education regarding vaccination and the prevention and control of disease.
Specific authorizing provisions related to childhood immunizations	By implication only. Statute does not require states to address all categories of preventive health services.
Authorized appropriations level Fiscal Year 1992	Such sums as may be necessary
Fiscal 1992 appropriations level	$297 million (includes vaccine stockpile)
Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations	Yes
Administering agency	Centers for Disease Control
Federal regulations	Yes 42 CFR § 51b.201, et seq
Agency guidance	Yes

11. Preventive Health and Health Services Block Grant Proaram

In 1981, Congress consolidated eight **categorical Public** Health Service programs into the Preventive Health Services Block Grant **program.**[149] This program is administered by the Centers for Disease Control within the Public Health Service. Funds formerly available to States under the categorical health programs would now be allotted by formula to the states to support a number of preventive, comprehensive and emergency health **services.**[150]

In addition to consolidating **categorial** preventive health services programs, Congress cut 1981 funding by almost half from the previous year level. In 1980, Congress appropriated about $170 million; in 1981 only about $93 million was **appropriated.**[151] Funding for the program remained stable from 1982 through 1991, when appropriations ranged from $79.1 million to a high of $90.9 million in 1991. Although the 1992 appropriation of $135 million considerably exceeds recent appropriations, this level still falls far short of the 1980 level.'[152] If adjusted for inflation over this time period, 1991 funding would have had to have been about $288.8 million to equal the 1980 funding **level.**[153]

The major drawback of this important statutory program is that states have complete discretion to expend block funds on any of the 12 authorized program activities. There is no statutory or regulatory mechanism to require states to address critical immunization needs. Indeed, the PHS Grants Administration Manual that interprets the health block grant programs, states the **following:**[154]

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[149] H.R. Conf. Rep. No. 97-208, 97th Cong., 1st Sess., 865 renrinted in 1981 U.S. Code Cong. & Ad. News 396,887. These programs were: health incentive grants, hypertension control, rodent control, school-based fluoridation, venereal disease control, family planning services, health education/risk reduction, and adolescent pregnancy services.

[150] 42 USC § 300w-3 (1991).

[151] Klebe, E.(October 24, 1991). CRS Report to Consress: Appropriations for Selected Health Proarams FY 1980-FY 1991. The Library of Congress, Congressional Research Service (91-769 EPW): Washington, DC.

[152] CRS, supra

[153] See Table 8 in Part I.

[154] **PHS Grants Administration Manual, Part 501, p.501-1.**

(a) The basic premise of the block grants is that the States should be free to target resources and design administrative mechanisms to provide services to meet the needs of their citizens.

(b) The very nature of the health block grant statutes implies that PHS is not to be actively involved in the administration of the statutory particulars. While HHS does have authority to promulgate regulation; that interpret statutory requirements, HHS has chosen to issue few regulations and to rely on State interpretation of the statutory language.

HHS has never promulgated any substantive regulations governing the administration of this health program.[155] There are no minimum service requirements and no uniform procedures for carrying out needs assessment or data collection on services provided.

During the 1981 amendments, many members of Congress and state health officials stated their fear that with flexibility to direct block grant funds, state administrators would emphasize certain health services and neglect others.[156] This unfortunate outcome appears to have happened with regard to immunization services. The most recent CDC Report to Congress on this grant program prepared by the Centers for Disease Control for Fiscal Year 1989 Report shows that states allocated the most block grant dollars to health education and risk prevention programs. Of the twenty largest spending categories reported by the states, spending on immunization was 15th. Only 8 states even reported a specific break out of funding for immunization services.

Thus, even in states that have low immunization rates, there is no statutory or regulatory mechanism in place that the Secretary might use to require a state to direct any portion of the preventive health block grant funds to such services.

In 1988, Congress extended the block grant program and appropriated funds for three more years and amendment some of its provisions.[157] Most notably, immunization services were specifically added to the authorized block grant programs.[158] The

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[155] The only regulations are those generally governing application and management of the block grant programs. See 45 CFR Part 96.

[156] Id. at 892.

[157] P.L. 100-607

[158] cite

legislative history of 1988 amendments states that the immunization services program [159] was added to "[c]larif[y] that States may use their Prevention Block Grant funds for immunization services."[160] Childhood immunization programs,' however appeared to be clearly provided for under the old categorical grants.[161] Specifically referring to low immunization rates, the House Report accompanying passage of the amendments[162] stated that "[a]lthough national immunization rates remain high, for low-income infants and children, vaccinations against such preventable diseases such as polio, measles, mumps, and whooping cough often are not readily available.

The 1988 amendments appeared to attempt to exert some influence over how the states spent preventive health block money.[163] These amendments required states to specify and describe the public health objectives they expect to attain with these funds. Previously, states merely had to describe the programs and activities they were funding with the block grant monies.

In 1992, Congress further extended and appropriated funds for this program and amended its provisions to provide more direction over use of these funds.[164] These amendments require states to use block grant funds to meet Healthy People 2000 objectives.

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[159] The statutes states that this phrases includes immunization services for emergency workers against preventable occupational-exposure disease such as hepatitis.

[160] H.R. Rep. No. 100-778 100th Cong., 2nd Sess., reprinted in 1988 U.S. Code Cong. & Ad. News 4167, 4226; H.R. Conf. Rep. No. 100-1055, 100th Cong., 2nd Sess., 6 reprinted in 1988 U.S. Code Cong. & Ad. News 4167, 4231. See Sec. 317(a)(2) of the Public Health Service Act. There is no information available describing any shifts in funding- to determine if more or less monies went for immunization programs prior to the consolidation.

[161] See § 317(a)(2), Public Health Service Act.

[162] No. 100-778

[163] For example, the FY 1989 Report to Congress shows that states directed significantly more funds to local health agencies under the block grant approach than under the categorical programs, but the report notes that states did not track the funds spent by the local health agencies.

[164] P.L. 102-531.

Although no specific objectives were highlighted by Congress in these most recent amendments, **congressional intent that these** funds should address immunization needs, as expressed during the 1988 amendments, is unmistakable. Whether the 1992 amendments will result in increased state use of funds for immunizations remains to be seen.

The agency may, however, have indirect methods available to influence state allocation of funds, particularly in view of the 1992 amendments that specifically incorporate the Healthy **People** 2000 objectives. For example, the Secretary is authorized to provide technical assistance to the states for planning and operating activities to be carried out with these funds. As part of providing technical assistance, the PHS **could point** out the need for immunization services, and show how such services may be most effectively provided either directly or through referral mechanisms. With such assistance, state may be persuaded to allocate funds for this purpose.

PREVENTIVE HEALTH AND HEALTH SERVICES BLOCK GRANTS

Program name and statutory citation	Preventive Health Services 42 USC 300w
General program structure	Grants to states, Indian tribes to provide "comprehensive preventive health services, including immunization services."
Specific authorizing provision related to childhood immunizations	No
Authorized appropriations level Fiscal Year 1992	None
Fiscal 1992 appropriations level	$135 million
Specific authorized funding earmark for immunizations	None
Specific appropriations earmark for immunizations	None.
Administering agency	HHS/CDC
Federal regulations	45 CFR Part 96
Agency Guidance	Yes, PHS Grant Administration Manual, Part 500, 501.

12. Stewart B. McKinney Homeless Assistance Act: Health Care for the Homeless

In 1987, Congress passed the Steward B. McKinney Homeless Assistance Act that authorized a number of programs designed to provide emergency food and shelter, transitional and longer term housing, primary and mental health care services, education, job training, and substance abuse services to the homeless and homeless families.[165] As part of the McKinney Act legislation, Congress amended Section 340 of the Public Health Service Act (Pub. L. No. 101-645) to provide for the delivery of health care to the homeless, specifically including funding for demonstration grants to deliver comprehensive primary health services to homeless children[166] and children at-risk for homelessness.[167]

According to a study by the Urban Institute, 15% of the homeless are children and 80% of all adults in homeless families are single women with children.[168] The General Accounting Office reports a one-day estimate of about 68,000 homeless children under 16.[169] Most homeless shelters will not accept unaccompanied youths and refer them to runaway shelters which may not offer the services needed by children with no homes from which to run away.[170] Because school attendance in this population may be as low as 43%, these children may be at highest risk for incomplete immunization.[171] The HCH program reports that among one group of homeless children, one-fifth had incomplete immunization.[172]

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[165] Pub. L. No. 100-77, Title I, § 102, July 22, 1987, 101 Stat. 484.

[166] Eligible children are 19 years old and under. Regional Program Guidance Memorandum 92-4, Attachment B, p. 4.

[167] See 42 USC 256 et seq. (1992.) See Outreach and Primary Health Services for Homeless Children, 42 USC § 256(s) (1992). A "homeless individual" under the statute is defined as a person "who lacks housing (without regard to whether the individual is a member of a family), including an individual whose primary residence during the night is a supervised public or private facility that provides temporary living accommodations and an individual who is a resident in transitional housing." 42 USC 256(r)(2).

[168] Ibid.

[169] Ibid.

[170] Ibid.

[171] Ibid.

[172] Ibid.

a. HUD Programs for the Homeless

In 1990, Congress reauthorized and increased funding for McKinney Act programs serving the homeless.'" Also, the categorical programs set out in the original legislation were revised because it was believed that this approach compromised the ability of agencies to provide comprehensive, coordinated services to this population.[174] In addition, the original programs were revised to reflect new congressional awareness that housing programs for special needs populations such as low-income families with children "must be more than bricks and mortar, . . . must include an appropriate package of supportive services."[175] The term "supportive services" is defined as including "child care", "outpatient health services."[176] Grantees may provide supportive services directly or by arrangement with local agencies.[177] Neither the legislation nor the regulations specifically mention immunizations, however, the supportive services definition, as well as the overall intention of the McKinney Act could readily be interpreted as including such basic health care for this extremely high-risk population. Agency guidance does not address immunization needs. A agency spokesperson indicated that few if any grantees in this program seek funds to provide services other than those directly related to shelter.

The Diversion of Public Housing Operating Funds program,"* administered by HUD, provides for the diversion of public housing operational funding to residents for economic self-sufficiency projects that might include health services. Under this program, residents may seek a waiver for use of funds for vacant public housing units and use such funds for non-dwelling economic self-sufficiency programs. Agency guidance states that typical services could include "child care facilities, adult day care ... and other services [of benefit to the residents] of the same nature may be approved."[179] Residents seeking the waiver, however, must demonstrate that the services they seek to fund are not available elsewhere.

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[173] Pub. L. No. 101-625,

[174] S.Rep. No. 101-316.

[175] Ibid.

[176] 42 USC § 11362 (1992).

[177] 42 USC § 11362(16)(D) 1992.

[178] 42 USC § 1437g (1992).

[179] HUD, Public and Indian Housing Notice PIH 90-39 (PHA).

b. HHS Programs for the Homeless

The Health Care for the Homeless (HCH) program and the Outreach and Primary Health Services for Homeless Children (Homeless Children) is administered by the Division of Special Populations Program Development within the Bureau of Health Care Delivery and Assistance (BHCDA). Although the legislation does not specifically mention immunization services, both statutory programs offer considerable potential to improve immunization rates among these populations. The grantees are required to provide "health services," defined as including preventive health services and well child services,[180] at locations accessible to the homeless."[181] Grant preferences favor applicants who are health care providers.[182]

No regulations have been promulgated for these programs. The agency guidance does not require that immunizations be offered to homeless adults or children but requires grantees to "respond to the preventive care needs of homeless patients"[183] and provide the homeless, either directly or indirectly, with "primary health care."[184] Grantees must provide homeless children with "comprehensive primary health care services."[185] The guidance defines "primary health care services" as including "preventive health services," "well-child services."[186] The guidance for the homeless children program defines "comprehensive primary health care" as including "preventive, episodic, and on-going care."[187]

Basic expectations for health services delivery include 24 hour, 7 day-a-week availability to the extent possible, use of mobile medical units and medical teams that visit shelters and soup kitchens, maintenance of medical and case management records, and

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[180] The statute refers to the definition set out in the Community Health Center statute. See 42 USC 254c(b)(1).

[181] 42 USC § 256(f)(l) 1992.

[182] 42 USC § 256(c) (1992).

[183] Regional Program Guidance Memorandum 92-4, p. 9.

[184] Regional Program Guidance Memorandum 92-4, p. 8.

[185] 42 USC 256(s)(l)(A) (1992).

[186] Ibid.

[187] Regional Program Guidance Memorandum 92-4, Attachment B, p. 6.

a staff experienced and trained in delivery of primary care.[188] Grantees are expected to provide for continuity of medical care for homeless children at stable locations, with routine schedules by the same medical team.[189]

In one instance, the homeless children program guidance specifically addresses immunization need in terms of needs assessment and states that applications should obtain data on incomplete immunizations in this population. Grantees must maintain medical records that includes primary care, demographic and other pertinent information and devise a method for tracking these children regardless of a change in shelter location or other living arrangement.[190]

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[188] Regional Program Guidance Memorandum 92-4, p. 12; Attachment B, p. 9.

[189] Regional Program Guidance Memorandum 92-4, Attachment B, p. 9.

[190] Id. at p. 11.

STEWART B. McKINNEY HOMELESS ASSISTANCE ACT

Program name and statutory citation	Provide housing and supportive services to homeless and their families. 42 USC § 11301 et seq.
General program structure	Grants to states, local governments, Indian tribes, non-profit orgs. to fund a variety of programs primarily devoted to providing housing assistance. Some of the programs include provision of supportive services including "health care" and "outpatient health services."
Specific authorizing provision related to immunization	No
Authorized appropriations level Fiscal Year 1992	About $690 million for all housing assistance programs; $30 million for costs of supportive services not covered by other funds under this statute--$lO,OOO limit per grant on funding for outpatient health services.
Fiscal 1992 appropriations level	About $450 million for housing and supportive services.
Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations	No
Administering agency	HUD/Office of Special Needs Assistance Programs
Federal regulations	24 CFR 90, 577-579; 34 CFR 425,441; 45 CFR 12, 1080
Agency Guidance	Grant applications request information on provision of "medical care;" but no specific guidance

HEALTH SERVICES FOR THE HOMELESS
(McKinney Act of 1987)

Program name and statutory citation	Delivery of primary health services to homeless individuals. Specific program for outreach and primary health services for homeless children. 42 USC § 256
General program structure	Grants to public and nonprofit entities (including some children's hospitals) to provide outreach and "comprehensive primary health services for homeless children, including rural children and children at "imminent risk" for homelessness; includes such services to be provided by "mobile medical units."
specific authorizing provision related to childhood immunizations	By implication. Statute states that the term "primary health services" shall have the same meaning as that given the term in 42 USC 254c(b)(1) which includes "services of physicians," "preventive health services," and "well child services."
authorized appropriations level, Fiscal 1992 and 1993	$5 million each year for homeless children's programs
Fiscal 1992 appropriations level	$56 million for overall program.
specific authorized funding earmark for immunizations	No.
specific appropriations earmark for immunizations	No.
Administering agency	HRSA with NIAAA and NIMH
Federal regulations	45 C.F.R. Parts 74 and 92

Agency guidance	Yes, Regional Program Guidance Memorandum 92-4

OPERATION OF LOW-INCOME HOUSING PROJECTS (DEPROGRAMMING OF UNITS)

Program name and statutory citation	Operation of Low-Income Housing Projects 42 USC § 1437g
General program structure	Operation of low-income public housing; statutory provision permits certain housing units to be taken out of residential use and the operating funds diverted for economic self-sufficiency uses that could include health care services.
Specific authorizing provisions relating to childhood immunizations	No
Authorized appropriations level, Fiscal 1992	Such sums
Fiscal 1992 appropriations level	2.5 billion (for entire low-income housing program)
Specific authorized funding earmark for immunization	No
Specific appropriations earmark for immunizations	No
Administering agency	HUD/Office of Resident Initiatives
Federal regulations	7 CFR § 226
Agency guidance	Yes, Public and Indian Housing Notice PIH 90-39 (PHA)

13. Indian Health Service Proarams

The Indian Health Service, an agency within the U.S. Public Health Service, administers several programs that provide and pay for immunizations for Native Americans. The agency's principal activities involve the direct provision of care through Service facilities, as well as purchasing services from contract providers located in urban and rural areas to care for Native Americans who do not have access to direct Services through the IHS.[191] In 1992 a three quarters of a million Native Americans reportedly were assisted through IHS-administered programs.

Statutory and Aaencv Standards for IHS-Funded Providers

Federal laws governing Indian health programs specifically authorize the Secretary of Health and Human Services, in administering health services programs, to use funds appropriated to the IHS for preventive health activities[192]. The highest priority is to be placed on tribes with the greatest proportion of "health resources deficiency" (i.e., the greatest levels of unmet health need)[193] The term "preventive" is not defined in the statute.

Regulations issued by the IHS specifically identify immunizations as a type of service that may be financed at IHS facilities with IHS appropriations.[194] But the rules do not require all IHS hospitals and clinics to offer immunizations.[195] Nor do the rules require contract providers furnishing services to Native Americans in urban and rural communities to provide immunizations as a basic primary care activities.*% Thus, while IHS authorizes the expenditure of funds for immunization activities, the on-site availability of immunization services for Native American patients of all ages is not a basic requirement for all IHS providers of

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191 25 USC §§ 1621 and 1651-1658 (1992).

192 25 USC § 1621(a).

193 25 USC § 1621(b) and (c)(1992)

194 42 CFR § 36.11(a)(1991).

195 42 CFR § 36.11 (b) and (c). The rule specifically provides that "the Service does not provide the same health services in each area served. The services provided to any particular Indian Community will depend on the facilities and services available from sources other than the Service and the financial and personnel resources made available to the Service." § 36.11 (c) (1991).

1% 42 CFR §§ 201 et seq and 350 et seq do not specify minimum service requirements for contract providers.

primary health care.

As a practical matter, while immunization services are not a requirement for all IHS-funded primary health care providers, Service officials appear to expect that immunizations will be widely offered to Native Americans through the IHS system. Notably, though, the Service's own Indian Health Manual never specifically mentions immunizations in its child health section.

The IHS Manual provisions governing maternal and child health services instruct providers furnishing "well-child" care to follow the Guidelines for Health Supervision issued by the American Academy of Pediatrics.[197] However, the AAP Guidelines (which are reprinted in the IHS manual) refer only generally to the ages at which children are to be immunized. These general Guidelines do not specify which vaccines are to be given at which age intervals; the more specific AAP instructions on immunizations are not included in the Guidance. Neither are the CDC Standards on Immunization Practice included.

Relationship Between the IHS Program and Medicaid

Native Americans are perhaps the single most underinsured sub-population in the United States. The very scarce resources which the IHS has to work with makes coordination with other sources of health care financing imperative. Yet IHS regulations do not require that all providers assisted through the IHS programs participate in Medicaid. Such a requirement would virtually guarantee a source of immunization financing to the IHS (not to mention financing for other health services) for large numbers of Native American children.

Moreover, even where IHS pediatric providers participate in Medicaid, no IHS rule requires all primary care providers to furnish Early and Periodic Screening Diagnosis and Treatment (EPSDT) services, the special package of Medicaid benefits for Medicaid enrolled children under age 21. Immunizations are a mandatory EPSDT service which must be paid for by all state Medicaid programs.[198] Were all IHS primary care providers to not only participate in Medicaid but also to furnish Medicaid EPSDT services, immunization services would, by definition, be available throughout the Service's programs.

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197 Indian Health Manual, Part 3, Ch. 13 (April 23, 1990).

198 42 USC § 1396d(r)(1)(1992).

Access to Vaccines

The IHS reports that a high proportion of Native American two-year-olds (between 85% and 90%) are fully immunized against preventable disease. This figure compares highly favorably -- indeed, they are more than double the immunization rates -- for two-year-olds living in inner cities.[199] These estimates may overstate the immunization status of Native American children, however, since they reflect the status of children treated by Service facilities rather than by contract providers.[200]

While the immunization data for Service facilities are impressive, officials indicate that vaccine supply has been a problem. Officials report that in most instances vaccine is provided by the state health agencies in which the IHS facilities are located. But at least one state health agency refuses to supply IHS sites with vaccines, (presumably because its own sites re experiencing shortages). Moreover, many state health agencies experience routine shortages. As a result, IHS facilities may be exposed to vaccine shortages.

The IHS is eligible to purchase vaccines directly from the manufacturers through the CDC bulk purchase contract.[201] However, it appears that the IHS buys vaccines for its sites through the contract only as a last resort -- that is, only if state health supplies are not forthcoming. While this policy may be consistent with the need to maximize resources (state vaccines may be furnished free-of-charge) it means that the Service may be unable to assure its facilities and contractors a steady supply of vaccine. Were contractors to be supplied directly by the Service, stronger vaccine expectations might be reasonable. The IHS purchasing policy also means that the agency may be vulnerable to the particular purchasing priorities of a specific state health agency, even though Native American patients may be vulnerable to specific vaccine-preventable illnesses.

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[199] "Access to Childhood Immunizations", op. cit. The NVAC reports that in a CDC study of immunization status, conducted between 1985 and 1986, of two-year-olds living in central cities, only between 27% and 40% were fully immunized by age two. These figures preceded the introduction of HIB and Hepatitis B, both of which necessitate additional injections of infants and toddlers, thereby potentially pushing full-immunization rates even lower.

[200] IHS officials indicated to the authors that they were without the legal authority to require contract providers to furnish immunization services. It is therefore not possible to know if all or most children in contract care are immunized.

[201] See Chapter 10, supra.

INDIAN HEALTH PROGRAMS

Program name and statutory citation	Indian Health Care 25 USC §1601 et seq.
General program structure	Series of provisions authorizing the Secretary to directly provide or purchase a range of health services for Native Americans. Programs codified at Chapter 16 of the Public Health Service Act include direct service programs to improve Indian health status, health promotion programs and contracts with urban and tribal health care organizations.
Specific authorizing provisions related to childhood immunizations	No: implicit in authority to Secretary to provide and pay for preventive health services.
Authorized appropriations levels Fiscal Year 1992	$20 million for Indian health services; $500,000 for health promotion activities; $6 million for contract services.
Fiscal 1992 appropriations level	$19.6 million for Indian health services; $3 million for health promotion activities; 0 for contract services.
Specific authorizing earmark for'immunizations	No
Specific appropriations earmark for immunizations	No
Administering agency	Indian Health Service
Federal regulations	42 CFR § 36.1 et seq.
Agency guidance	No specific discussion of immunizations in agency manual.

14. Native Hawaiian Health Care

The Native Hawaiian Health Care program was originally enacted in 1988. The purpose of the Act is to assure the availability of comprehensive health promotion and disease prevention services for Native Hawaiians. The Act requires the development of a comprehensive master health plan for Native Hawaiians in order to assure health promotion and disease prevention. The Secretary is then authorized to make grants to Hawaiian health centers, Native Hawaiian organizations, and other public and private non-profit entities for the provision of certain services: outreach, health education, and a series of primary health services, including immunization services.[202]

In structure, the service delivery provisions of the Act most closely resemble the community and migrant health centers programs in their statutory service specificity. In 1992 a total of----- providers received Native Hawaiian Health Care grants. Of' these also received funding under the community health centers program.

The Native Hawaiian program is administered by the Bureau of Health Care Delivery Assistance (BCHDA), within the Health Resources and Services Administration. This is the same Bureau that administers the health centers programs. Thus, the guidance and standards for immunization proactive which BCHDA follows in administering the health centers programs presumably also apply to Native Hawaiian programs that are not already BCHDA grant recipients under another funding authority.

As with health centers programs (and consistent with the statutory structure of the Act) immunizations are a required service for all Native Hawaiian grantees.[203] Furthermore, as with health centers, all Native Hawaiian grantees must participate in Medicare and Medicaid. Thus to the extent that Medicare and Medicaid pay for immunization services, these funds can be used to supplement the special grants received.[204]

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[202] 42 USC § 11703(c)(1)(D)(1992).

[203] Bureau of Primary Health Care, Program Guidance: Health Care for Native Hawaiians (August, 1992) p. 10.

[204] It should be noted that, as discussed in the ERISA chapter above, Hawaii is the only state in the country that currently requires insurance coverage for all residents, either through an employer plan or through a public program. The extent to which private plans pay for immunization services would be governed by state law, which sets minimum standards for all insurance provided to residents.

Like other HRSA-administered programs, Native Hawaiian clinics potentially are eligible for all medically necessary vaccines purchased by HRSA at the CDC contract price.[205] There is no indication that Native Hawaiian clinics receive inadequate amounts of vaccines from the state health agency, however.

[205] See discussion in Chapter 10.

NATIVE HAWAIIAN HEALTH CARE

Program name and statutory citation	Native Hawaiian Health Care, 42 USC § 11701 et seq.
General program structure	Grants to develop a Native Hawaiian comprehensive health care master plan and to fund Native Hawaiian health centers for comprehensive health promotion and disease prevention services. Qualified grantee entities are Native Hawaiian Health centers, Native Hawaiian organizations, and public and. private non-profit health providers.
Specific authorizing provisions related to childhood immunizations	Yes. 42 USC § 11703(c)(l)(D) specifically identifies immunizations as a mandatory service.
Authorized appropriations, level Fiscal Year 1992	$10,000,000
Fiscal 1992 appropriations level	$3.596 million
Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations	No
Administering agency	Health Resources and Services Administration, Public Health Service.
Federal regulations	No
Agency guidance	Guidance specifies that immunizations are required but no specific content requirements.

15. Public Housins Primarv Care

This program, jointly administered by BHCDA and the Office of Minority Health, funds projects to develop responsive primary health care delivery systems for residents of public housing developments.[206] Health services may be delivered directly or through contracts. Service delivery models are expected to be comprehensive and to address the special health problems that affect families and children living in public housing.[207] Program goals specifically include provision of immunization services. Although the statute itself is silent regarding immunization services, agency guidance states that grant applicants are required to provide preventive care services including immunizations.[208] The guidance, however, does not specify age groups[209] or types of immunization services nor makes any reference to CDC immunization protocols.

Through the use of demonstration grants, this program is intended to support innovative, community-based programs for the delivery of comprehensive outreach, primary health and referral services to homeless children[210] and children at imminent risk[211] for homelessness and their parents/guardians at locations accessible to this group. Eligible applicants are private non-profit and public agencies and children's hospitals.[212]

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[206] 42 USC § 256a (1992).

[207] Regional Program Guidance Memorandum 92-24.

[208] Ibid.

[209] Grantees are required to file annual reports that include separate information categories for immunizations services provided to children from 0-2 and 3-6.

[210] Regional Program Guidance Memorandum 92-4 defines "children" as those age 19 and under.

[211] Regional Program Guidance Memorandum 92-4 describes children at "imminent risk" of homelessness as including:
(1) children living in precarious housing situations, e.g. in a family which is in unstable or inadequate housing;
(2) children in foster care systems who have difficulty accessing health services;
(3) children living with relatives or other adults not their parents;
(4) unattached adolescents.

[212] 42 USC § 256(s)(2).

The service delivery must be fully integrated through coordination of care and case management, an essential component of this program. Case management is described as a process for integrating health care and other social and support services for homeless children and their families that includes input from each member of the health care team including physicians, nurses, social workers, case managers, outreach workers, nutritionists and others.[213]

[213] Regional Program Guidance Memorandum 92-4.

PUBLIC HOUSING PRIMARY CARE

Program name and statutory citation	Public Housing Primary Care (PHPC) also known as Health Services to Residents in Public Housing 42 USC 256a
General program structure	Grants to provide, directly or by contract, primary health services, including health screening, health counseling and education services at public housing developments or locations immediately accessible to these residents
Specific authorizing provisions relating to immunization services	By implication. Agency guidance requires grantees to provide immunizations.
Authorized appropriations level, Fiscal 1992	Such sums
Fiscal 1992 appropriations level	$6 million
Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations	No
Administering agency	**HHS/BHCDA/OMH**
Federal regulations	None
Agency guidance	Yes, Regional Program Guidance Memorandum 92-24

16. Head Start Programs

a. Head Start

The Head Start program provides grants to local agencies to develop comprehensive child development services to children in low income families who have not yet reached the age for compulsory school attendance. In 1992 infants, toddlers and children were served by Head Start. Of these, only a small proportion are under age 2. However, many Head Start children have younger siblings in what is perhaps the most crucial age range for immunization services.

Along with WIC and child care programs, Head Start is of paramount importance because it is one of the few large federal programs that reaches preschool age children, and their siblings and other family members in organized settings in which immunizations and other preventive health services can be furnished. The crucial developmental time period that Head Start serves, along with its broadly defined mission to address the health, educational, nutritional and social services of economically disadvantaged children[214] makes the program a launchpad of any systematic federal effort to immunize young children.

Head Start funds are targeted on the most at-risk children. Additionally, certain subpopulations of poor children are specifically targeted for head Start. These include migrant children and Native American children. Additionally, a special demonstration between Head Start and the United States Department of Housing and Urban Development provides $4.8 million for 17 Head Start grants to develop programs in public housing for infants, toddlers and children ages 3 to 5.

The Head Start program is administered by the office of Human Development Services within the Department of Health and Human Services, Administration on Children and Families. Federal implementing regulations set forth comprehensive requirements regarding the health services which all grantees must provide.[215] These services include a "broad range of medical, dental, mental health and nutrition services to preschool children, including handicapped children, to assist the child's physical, emotional, cognitive and social development toward the overall goal of social competence.[216] Grantees are also required to promote preventive

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[214] 42 USC § 9831

[215] 45 CFR § 1304.3-l (1992).

[216] 45 CFR § 1304.3-1(a) (1992)

health services and early intervention.[217]

Programs specifically are required to furnish the following health services:

- health assessments which include assessment of current immunization status[218];
- medical examinations[219]; and
- health education.[220]

Additionally, grantees must provide for treatment and follow up services which specifically include "completion of all recommended immunizations.[221] While federal regulations require that all recommended immunizations be furnished, the rules have not been updated to include either HIB or Hepatitis B vaccinations.

Guidance furnished to the authors by the Head Start Bureau in July, 1992, as a supplement to the regulations is dated June, 1988, and therefore apparently had not yet been updated to include these two vaccines. However, agency official indicated that updated guidance would be sent to grantees prior to the beginning of the school year. Program performance standards now being drafted by the agencies provide that all grantees must provide or arrange for the completion of all recommended immunizations of the Public Health Service Committee on Immunization Practice (ACIP). Presumably the standards will describe what these standards entail, since many grantees may be unaware of the addition of the two vaccines and my also be unaware of the exact schedule for immunizations.

The emphasis on parental involvement means that the health education component of Head Start offers an excellent opportunity to inform families about the importance of immunizing children and the need to vaccinate children numerous times in order to assure complete immunization status. The health education program also could be used to explain to families the risks and benefits of immunization, address concerns parents might have about the safety of vaccines and to help families be aware of potential reactions to vaccines.

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217 45 CFR § 1304.3-1(b) (1992).

218 45 CFR § 1304.3-3 (b)(8) (1992).

219 45 CFR § 1304.3-3(c) (1992).

220 45 CFR § 1304.3-6 (1992).

221 45 CFR § 1304.3-4(a)(2) (1992).

b. Head Start Transition

Like Head Start, the Head Start Transition" and Follow Through" programs are designed to furnish comprehensive educational, health, nutritional, social and other services to children previously enrolled in Head Start or similar "quality preschool programs."[224] The programs are to be focused on children in kindergarten and primary grades who come from low income families. Grantees are specifically authorized to furnish services during times when schools are not in session and in sites other than schools. As with Head Start, the Transition and Follow Through programs require a high degree of parental involvement.

Specific issues

1. Funding an on-site vaccination program: The federal government requires that Head Start funds not be used for immunizing children unless no other funds are available. Options open to a Head Start agency include referring children to sources of free or reduced cost vaccination services or developing an immunization program on-site. The latter approach may be particularly useful in assuring that children in fact complete their immunization services and as a means of reaching the siblings of Head Start children.

In order to financing an on-site vaccination program, as well as pay for the cost of furnishing other preventive health services, significant funds must be secured. The ideal source of financing is Medicaid, since , under the recent program expansions, virtually all Head Start children will be entitled to coverage. Medicaid coverage for children entitles them to a comprehensive set of health benefits known as Early and Periodic Screening Diagnosis and Treatment (EPSDT) services. As discussed at greater length in Chapter 6, EPSDT covers comprehensive health exams, health education, immunizations and assistance in providing or arranging for needed health care.

State Medicaid programs could arrange for out-stationed enrollment in Medicaid at Head Start programs.[225] Service could then be provided by a nurse or mid-level practitioner employed by a Head Start agency or by a health professional employed by another agency (such as a local health department or community health center) who furnishes care on-site and is reimbursed by Medicaid.

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[222] 42 USC § 9855a(1)

[223] 42 USC § 9861

[224] 42 USC § 9861.

[225] See Chapter 6 for a discussion of out-stationed enrollment.

Cooperating physicians in private practice also could furnish care in Head Start locations.

A survey conducted by the Children's Defense Fund in 1991 revealed that among 49 reporting states and the District of Columbia[226] less than half specifically recognized Head Start agencies as qualified EPSDT screening providers. Moreover, while virtually all Medicaid programs pay for EPSDT services when furnished by staff of health agencies or health centers, HCFA has taken the position that services furnished by staff employed at clinics is not reimbursable as a clinic service when furnished off-site. It is important that HCFA amend this policy to specifically exempt health centers and local health agencies from this restriction.[227]

HCFA and the Head Start Bureau could issue joint guidance to all grantees and to Medicaid agencies detailing procedures for payment for EPSDT assessment and immunization services at Head Start programs. Additionally, HCFA could develop out-stationed Medicaid enrollment guidance for Medicaid agencies that uses head Start agencies as a model.

2. Immunization and Medicaid enrollment for siblings and preunant women in Head Start families: All Head Start programs could provide immunization and assessment services not only to enrolled children but to the pregnant women and siblings of enrollees. Additionally, outstationed Medicaid enrollment could be offered to all pregnant women and children in Head Start families.

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[226] Georgia did not respond to the survey.

[227] The prohibition against of-site clinic services is implied by HCFA from the definition of "clinic services", which is contained in the Medicaid statute itself. 42 USC § 1396d(a)(9). However, the statutory language which (according to HCFA) gives rise to this limitation pertains only to certain clinics. The statutory provisions creating the federally qualified health centers programs (which covers all federally funded and certain other community health centers), as well as the provisions allowing reimbursement for services of local health agencies, are found in a different section of the statute. Therefore, the prohibition against off-site services does not appear to apply to these providers. HCFA should thus clarify that where off-site providers are employees of health departments or health centers, Medicaid reimbursement may be claimed in non-clinic settings. In the case of physicians, the limitation does not apply.

3. Manaaed care and Head Start: With increasing frequency, children enrolled in Head Start will be enrolled in Medicaid managed care arrangements. These arrangements specify that some or all services covered by Medicaid state plans (including EPSDT services) must be provided through the managed care plan providers.

It is extremely uncommon to find managed care plans that sub-contract with Head Start programs (or clinics serving head Start programs, as many do) to furnish EPSDt in these alterative settings. It is not uncommon for Head Start agencies to experience difficulty in getting prompt appointments for children with their managed care plans.

An extremely important activity for HCFA, therefore, is guidance to states on expected relations between Head Start and managed care. All managed care plans should be encouraged to arrange for the provision of on-site services to Head Start children through sub contracts with Head Start programs to offer on-site services. Additionally, plans should be required to make check-up and immunization appointments promptly available to Head Start (and other child care) programs.

HEAD START PROGRAMS

Program name and statutory citation	Head Start Programs 42 USC § 9831 et sea.
General program structure	Financial assistance to Head Start agencies for the provision of "comprehensive health, nutritional, educational, social, and other services" to aid pre-school age children "attain their full potential."
Specific authorizing provisions related to childhood immunizations	No.
Authorized appropriations level Fiscal Year 1992	$4.273 billion.
Fiscal 1992 appropriations level	$2.202 billion.
Specific authorized funding earmark for immunizations	No.
Specific appropriations earmark for immunizations	No.
Administering agency	DHHS, ACF, ACYF
Federal regulations	45 CFR § 1304 et seq.
Agency guidance	Yes, Head Start Program Performance Standards (DHHS Publication No. (ACF) 92-31131; DHHS, ACYF, HDS, Information Memorandum of June 3, 1988, "Update to Current Head State Immunization Policy"

HEAD START TRANSITION PROJECT

Program Name and Statutory Citation	Head Start Transition Project 42 U.S.C. 9855 **et seq.**
General Program Structure	Provide funds for demonstration projects by Head Start agencies, parents, local educational agencies to develop successful strategies for provision of continuing comprehensive supportive services to low-income children entering kindergarten up through grade 3 to determine if provision of such services maintain and enhance the benefits attained by Head Start children.
Specific authorizing provisions related to childhood immunizations	Yes, "supportive services" statutorily defined to include **"immunizations."**
Authorized appropriations level Fiscal Year 1992	$20 million
Fiscal 1992 appropriations level	$20 million
Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations	No
Administering agency	DHHS, ACYF, ACF,
Federal regulations	45 CFR 1301-05
Agency guidance	Yes. Program Announcement No. ACYF-HS-93600.91-3. Availability of FY 1991 Funds and Request for Applications; Head Start/Public School Early Childhood Transition Demonstration Projects.

FOLLOW THROUGH

Program name and statutory citation	Follow Through 42 USC § 9861 et seq.
General program structure	Project grants to school boards, local education agencies (LEAs), other eligible organizations, to assist in meeting costs of comprehensive education, health, nutrition, parental involvement, other services for low-income children in kindergarten through grade 3, who have participated in Head Start or comparable pre-school programs; eligible organizations may include public or private non-profit entities including colleges and universities capable of reaching children, such as those in private schools, that the LEA does not reach; priority for projects in schools qualifying for federal funding for educationally disadvantaged students (Chapter I).
Specific authorizing provisions related to childhood immunizations	By implication only; projects are to provide comprehensive services, including health.
Authorized appropriations level Fiscal Year 1992	Such sums as may be necessary.
Fiscal 1992 appropriations level	$8.6 million
Specific authorized funding earmark for immunizations	No.
Specific appropriations earmark for immunizations	No.
Administering agency	Office of Elementary and Secondary Education, Department of Education.
Federal regulations	7 CFR § 215 et seq.
Agency guidance	No.

17. Adolescent Family Life

The Adolescent Family Life program was enacted in 1981 to address the problems of teenage sexual behavior and pregnancy.*** The program funds demonstration projects to prevent adolescent pregnancy and assist pregnant adolescents and adolescent parents. A 1992 HHS/AFL Fact Sheet states that "15,000 pregnant and parenting adolescents and their families are served each year by AFL care projects."

While the primary focus of the program is prevention services to reduce teen pregnancy, the statute clearly contemplates provision of a variety of health services including "primary and preventive health services"[229] to adolescents and their families.[230] The statute also accords priority to applicants that propose to locate AFL facilities in "primary health care centers."[231] The statute does not specifically address immunization needs but authorizes the Secretary to determine specific services grantees are to provide.[232] No regulations, however, have been promulgated for this program. The agency has recently issued guidance for grant applicants in which the Secretary specified that grantees must provide 10 required services to clients.[233] Although these services include "primary and preventive health services," there is no specific mention of immunizations. The grant guidance also advises that services to adolescents[234] and their children should continue for two years after birth, a period during which immunizations could be provided.

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[228] 42 USC § 3002 et seq. (1992). In fiscal year 1991, AFL funded 57 care and prevention programs and 6 research projects with sites in 30 states and Puerto Rico.

[229] 42 USC § 300z-1(4)(c). (1992).

[230] The statute defines a person eligible for these services as "a pregnant adolescent, an adolescent parent, or the family of a pregnant adolescent or an adolescent parent." 42 USC § 300z-l(a)(2) (A) (1992).

[231] 42 USC § 300z-4(a)(4).

[232] 42 USC § 300z-1(5)-(7) (1992).

[233] 57 Fed. Reg. 3506 (January 29, 1992).

[234] The grant guidance defines the population eligible for AFL services as "pregnant adolescents and adolescent parents under 19, [emphasis to be placed on those 17 years old and younger], their families, and young fathers and their families."

While this Federal program has considerable potential to address immunization and is targeted at a population likely to be at high-risk for lack of immunization, it is unfortunate that there are no regulations or guidance requiring grantees to screen and provide immunizations.

There are several broad statutory and regulatory provisions that expressly or impliedly refer to health care needs of teenage parents, their children and family members. In addition, the statute explicitly recognizes that "a wide array of educational, health, and supportive services are not available to adolescents. . . or to their families, or when available frequently are fragmented and of limited effectiveness."[235] Another provision states that' "Federal policy therefore should encourage the development of appropriate health, educational and social services."

Thus, it appears that funds available under this program could be used for direct or referral provision of childhood immunization and grantees service clients likely to be at high-risk for lack of immunization.

[235] 42 USC § 300z(9).

ADOLESCENT FAMILY LIFE PROGRAM

Program name and statutory citation	Adolescent Family Life (AFL) Program 42 USC § 3002 et seq.
General program structure	Provides funds for demonstration and research projects to develop strategies to address the problems of teenage sexual behavior and pregnancy and provide services to pregnant and parenting adolescents and their families.
Specific authorizing provisions related to childhood immunizations	No.
Authorized appropriations level Fiscal Year 1992	None.
Fiscal 1992 appropriations level	$7.761 million.
Specific authorized funding earmark for immunizations	No.
Specific appropriations earmark for immunizations	No.
Administering agency	DHHS/Office of Adolescent Pregnancy Programs (OAPP).
Federal regulations	None.
Agency guidance	Yes, Application Kit for AFL Demonstration Program Grants.

18. Family Planning Services

Congress enacted the Family Planning Services and Population Research Act of 1970 to assist persons in obtaining the information and means to exercise personal choice in determining the number and spacing of their children. The program awards grants to public and non-profit state agencies to establish projects that provide educational, and comprehensive medical and social services necessary for adequate family planning[236] serves adults and adolescents. Low-income individuals receive free services, other clients pay according to a fee 'schedule based upon ability to pay.[237] In 1989, 4,000 clinics received funding under this program and 4.3 million persons received services.[238]

This program has the potential to address and promote immunization for clients of family planning clinics even though its primary focus is upon reproductive and contraceptive services. Agency program guidance states the following:[239]

> For many clients, family planning programs are their only continuing source of health information and medical care. Therefore, while most of the client services will necessarily relate to fertility regulation, family planning programs, should, whenever possible, provide health maintenance services such as screening, immunization, and general health education and counseling directed toward health promotion and disease prevention.

However, it is not clear whether family planning clinics could provide immunizations to infants and children of clients. There is no specific definition of the intended service population in the statute, the regulations or the agency guidance.

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[236] 42 CFR §§ 59.1, 59.3.

[237] 42 CFR § 59.5(7), (8).

[238] H. Rep. No. 101-999, 101st Cong., 2d Sess. 204 (1990).

[239] U.S. Dept. of Health and Human Services, Public Health Service, Health Services Administration, Bureau of Community Health Services. Proaram Guidelines for Project Grants For Family Planning Service, p. 14.

FAMILY PLANNING SERVICES

Program name and statutory citation	Population Research and Voluntary Family Planning Programs 42 USC § 300
General program structure	Grants to public and private nonprofit family planning services agencies to provide a "broad range of acceptable and effective family planning methods and services."
Specific authorizing provisions relating to childhood immunizations	No. Agency guidance, however, states that for many clients family planning services may be only health care source so that health maintenance services including screening, education, and "immunization, should be provided to promote health of clients and "their infants and children."
Authorized appropriations level, Fiscal 1992	None
Fiscal 1992 appropriations level	$150 million
Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations	No
Administering agency	DHHS, Office of Population Affairs
Federal regulations	42 CFR § 59
Agency guidance	Yes, Program Guidelines for Project Grants For Family Planning Services

19. Community Service and Community Development Block Grant

The Community Service Block Grant program authorizes grants to state Community Action Agencies to ameliorate or eliminate poverty. The statute permits grantees to offer a wide range of services including the "need for health services."[240] Thus, grantees could provide immunization services under this program. The statute expressly precludes the Secretary from prescribing how states use these funds, however. There are no regulations governing this program other than the rules applying to all PHS block grants at 45 CFR 96. There is a one-page letter to grantees that is the sole agency guidance available. There is no reference to provision of any health services. Given the large amount of funding for this program ($437 million in FY 1992), there should be far more substantial agency guidance available to grantees that highlights the authority to provide health services under the statute and that brings attention to the need for immunizations in low-income populations.

The Community Development Block Grant program authorizes grants to states, local governments and Indian tribes for the provision of public services, that include child and health care, to benefit persons of low and moderate income.

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[240] 42 USC § 9904 (1992).

COMMUNITY SERVICES BLOCK GRANT

Program name and statutory citation	Community Services Block Grant Program 42 USC § 9901
General program structure	Grants to states to ameliorate the causes of poverty in its communities
Specific authorizing provisions related to childhood immunizations	No
Authorized appropriations level Fiscal Year 1992	$460 million
Fiscal 1992 appropriations level	$437.4 million
Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations	No
Administering agency	HHS/ACF
Federal regulations	45 CFR § 96
Agency guidance	Yes, Program Announcement No. OCS-92-04, Request for Applications Under the Office of Community Services' Fiscal Year 1992 Demonstration Partnership Program, 57 Fed. Reg. 18236 (April 29, 1992).

20. Juvenile Justice

Since 1974, the Department of Justice, Bureau of Prisons, has been authorized to administer a correctional program for juvenile offenders.[241] This program states that every juvenile offender in a correctional facility has the right to a number of basic care services including medical care.[242] This program contemplates that juveniles will be placed in community-based facilities such as halfway houses and foster homes, provision of medical care is through contract services or referral. Juveniles are housed in community-based correctional centers that bid for contracts with the Bureau of Prisons (BOP). BOP contract award standards require contractors to provide juveniles with necessary medical care and to conduct an intake medical examination. There is no specific mention, however, of immunizations.

In 1974, Congress also passed the Juvenile Justice and Delinquency Prvention Act that provided formula grants to the states to develop and improve services designed to prevent and rehabilitate juvenile delinquents, to divert juvenile offenders away from adult correctional institutions into community-based facilities specifically intended for this population, and to develop national program standards.[243] The statute defines the type of "community-based" facility intended for juvenile corrections as one that offers a number of basic care services including "medical care." There is no definition of this term in the statute. A specific goal of the program is to provide federal technical assistance and development of standards and guidelines for juvenile prevention programs. There are no regulations for this program. There is no specific agency guidance on medical care or immunizations for this program.

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[241] 18 USC § 5031 et sea. (1992).

[242] 18 USC § 5039.

[243] 42 USC § 5601 et seq. (192).

CORRECTION OF YOUTHFUL OFFENDERS PROGRAM

Program name and statutory citation	Correction of Youthful Offenders 18 USC § 5031 et seq.
General program structure	Administration of correctional programs for juvenile offenders. Program requires that juvenile correctional institutions provide a number of basic services including medical care. Agency contract award standards require contractors to provide juveniles with necessary medical care and to conduct an intake medical examination.
Specific authorizing provisions related to immunizations	By implication only.
Authorized appropriations level Fiscal Year 1992	Such sums
Fiscal 1992 appropriations level	$3,790,460
Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations	No
Administering agency	Department of Justice, Bureau of Prisons
Federal regulations	28 CFR Chapter V
Agency guidance	Yes, but no specific mention of immunizations

JUVENILE JUSTICE AND DELINQUENCY PREVENTION

Program name and statutory citation	Juvenile Justice and Delinquency Prevention Act 42 USC § 5601 *et sea.*
General program structure	Formula grants to the states to administer and improve their juvenile correctional programs
Specific authorizing provisions related to immunizations	By implication only.
Authorized appropriations level Fiscal Year 1992	Such sums.
Fiscal 1992 appropriations level	$76 million
Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations	No
Administering agency	Department of Justice, Office of Juvenile Justice and Delinquency Prevention
Federal requlations	None
Agency guidance	No specific reference to immunizations

21. Special Supplemental Food Proaram for Women. Infants and Children (WIC)

Enacted in 1972 as an amendment to the Child Nutrition Act of 1966, the WIC program, administered by the Food and Nutrition Service (FNS) of the U.S. Department of Agriculture is the nation's largest public health and nutrition program operating in all 50 states, the District of Columbia and U.S. territories.[244] The Secretary of Agriculture recently stated that the WIC program serves one in three babies born each year in the United States.[245] There is no comparable health services program for babies.

As of June, 1992, FNS data indicate that the FY 1991 WIC program had an average monthly participation of 5.3 million individuals, up from 4.5 million participants in FY 1990, and 3.8 million participants in 1989. In 1974, WIC had an average monthly participation of 87,657. Despite the huge increase in the numbers of women and children enrolled in the WIC program, estimates indicate that only about half of those eligible for participation receive WIC services. This appears to be a direct result of appropriations levels.[246]

WIC is currently extended through 1995 under the authority of the Child Nutrition and WIC Reauthorization Act of 1989 with appropriation levels authorized at "such sums as necessary for each of the fiscal years 1991 - 1994".[247]

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[244] Sargent, J.D., Attar-Abate, L., Meyers, A., Moore, L., Kocher-Ahern, E.(1992). Referrals of Participants in an Urban WIC Program to Health and Welfare Services. Public Health Reports, 1992 3 - 1 7 8 .

[245] Federal News Service, February 11, 1992, Remarks of Agriculture Secretary Edward Madigan to the Surgeon General's Conference on Healthy Children Ready to Learn, Washington, DC.

[246] The National Advisory Council on Maternal, Infant, and Fetal Nutrition reports that in 1980, 1982 and 1984 it recommended to the President and Congress that WIC funding be set at levels that would permit service to 50% of eligibles. In 1986, 1988 and 1990, the Council recommended that WIC funding be incrementally increased by 10% each fiscal year until the program serves 100% of those eligible. In 1992, Congress increased the WIC authorization to permit the program to service additional eligible clients.

[247] 42 USC § 1786(g)(l).

Cited in the House Report as one of the government's most cost effective programs[248], its current fiscal 1992 appropriations level is $2.6 billion.[249]

Although the primary purpose of the WIC statute is to provide eligible pregnant, postpartum and breastfeeding women, infants and children up to 5 years of age with supplemental foods and nutrition education at no cost, Congress directed the WIC program to "serve as an adjunct to good health care during critical times of growth and development, to prevent the occurrence of health problems .. and improve the health status of these persons."[250] Indeed, Congress expressly recognized that the health of "substantial numbers" of these women and their children is at "special risk" due to "inadequate income" and "inadequate nutrition or health care, or both."[251] The statute requires that WIC agencies coordinate with "immunization programs"[252], "well child care," "maternal and child health care," and "Medicaid programs."[253] The WIC regulations specifically require coordination with the Early and Periodic

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[248] Child Nutrition and WIC Reauthorization Act of 1989, House Report, 1989 U.S. Code Cong. & Ad. News, 650.

[249] 102 P.L. 142; 1991 H.R. 2698; 105 Stat. 878.

[250] 42 USC § 1786 (1991).

[251] 42 USC § 1786(a) (1991) (emphasis added).

[252] The statutory provision requiring states seeking funds to expressly include immunization coordination for WIC participants in their plans was added to the statute in 1978. Child Nutrition Amendments of 1978, Pub. L. No. 95-627, 92 Stat. 3603. There is no discussion of this language in the House Reports accompanying these amendment. H.R. Rep. No. 95-1153(I), H.R. Rep. No. 95-1153(II), 95th Cong., 2d Sess., reprinted in 1978 U.S. Code Cong. & Ad. News 9227. However, hearings held on the amendments contain two references by state WIC officers to the effect that WIC participation has resulted in greater screening and utilization of health services, including immunizations. Child Nutrition Amendments of 1978: Hearinas on S. 2630, S. 2809. S. 2824 Before the Subcomm. on Nutrition of the Senate Committee on Agriculture, Nutrition, and Forestry, 95th Cong., 2d Sess. 221, 360 (1978) Regulations addressing the 1978 amendments were promulgated a year later but there is no discussion of or comment on the immunization provision in either Notices of Proposed Rulemaking or Final Action. See 44 Fed. Reg. 44422 (January 9, 1979); 44 Fed. Reg. 2114 (July 27, 1979).

[253] 42 USC § 1786(f)(1)(C)(iii).

Screening, Diagnosis and Treatment Program and the Maternal and Child Health Program.

There is no specific agency guidance in the regulations or elsewhere that details what WIC staff must do to carry out the required immunization coordination activities. A 1988 FNS report indicates that 45 percent of WIC recipients received immunizations through WIC referral. The same report showed that 31 percent of WIC sites provided on-site immunizations.

The regulations govern the use of WIC funds.* None of the authorized uses for WIC funds cover purchase of vaccines or personnel costs associated with provision of medical care. Discussions with WIC staff at the FNS indicated that the agency views the WIC program as providing health care **referrals,**[255] not as a direct source of health care, although there has been recent agency attention given to **immunizations.**[256] WIC regulations establish eligibility priorities for local agency participation

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[254] 7 CFR 5246.14 (1992).

[255] There is no data available that indicates the degree to which health care referral under WIC results in successful outcomes (i.e. receipt of immunizations). Sargent, **supra**, n. 1.

[256] In June, 1990 **U.S.D.A.'s** Food and Nutrition Service (FNS) and **CDC's** Division of Immunization initiated a cooperative effort to increase immunization rates among pre-school age **WIC** participants who are 12 months through 2 years of age. To initiate the program the following steps were taken:

The Assistant Secretary for Food and Consumer Services, USDA and the Assistant Secretary for Health at PHS/DHHS sent a joint letter encouraging increased cooperation to all State Health Commissioners; FNS began to develop specific action steps to improve access to immunization services for WIC participants;

FNS is emphasizing coordinated efforts be considered a Program priority; FNS regional offices were asked to review local WIC agency efforts to promote improved immunizations; In August 1990, FNS asked State WIC Directors to aggressively promote measles immunization for WIC participants in the targeted age group;
In September 1990, all FNS Regional Administrators were urged to begin regional initiatives to improve immunization rates;
CDC, in conjunction with several state agencies is conducting demonstration projects to explore various means of increasing immunization rates.

There is no available data to assess the success of these coordination efforts to improve immunization.

stating that states shall first consider for funding a "public or private nonprofit health agency that will provide ongoing, routine pediatric and obstetric care and administrative services."[257] Other eligible local agencies must enter into agreements with health care providers to provide services or must refer WIC participants to health care providers.[258]

Eligible participants in the program must meet income eligibility standards in conjunction with nutritional risk criteria.[259] Individuals eligible under the Food Stamp program, Aid to Families with Dependent Children (AFDC) and Medicaid are deemed eligible for WIC participation.[260]

In sum, WIC is a very large federal program with a health care referral mandate that serves a high-risk, often hard-to-reach population on a repeated and consistent basis[261] usually at sites with health care facilities. Accordingly, the WIC program has significant potential to improve immunization status.

An analysis of the WIC program indicates that the following are positive features that could significantly promote childhood immunization efforts:

--specific mention of immunization referral;

--WIC voucher and counseling programs promote continuous contact with participants;

--maintenance of participant medical records;

--outreach efforts to potential participants, including the homeless, migrants, shelters for victims of domestic violence;

--follow up on pregnant women who miss appointments;

--WIC eligibility determination portable;

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[257] 7 CFR § 246.5(d)(l)(i) (1992).

[258] 7 CFR § 246.5(d)(l) (1992).

[259] The WIC regulations set out priorities for WIC recipients. 7 CFR §246.7(d)(4). First priority goes to pregnant and breastfeeding women and infants at nutritional risk.

[260] 42 USC § 1786(d)(2)(A)(ii)(I), (II), (III).

[261] For example, recipients arrive at WIC clinics to receive foods voucher on a monthly or bimonthly basis.

. --required nutritional risk assessment may be by a health care provider;

--specific funds earmarked for improvement of State WIC data systems;

--local health clinics receiving top funding priority;

--WIC agencies must take reasonable steps to communicate in native language of participants;

--transportation costs of rural participants are covered;

--WIC counseling sessions educate young parents about importance of immunization.[262]

--recent cost-containment efforts in food (infant formula) purchase by WIC agencies has freed funds to serve more clients.

The following features of the WIC program, however, may act as barriers to provision of immunizations:

--WIC funding has supported only 50% of eligible participants;

--participants must apply and be deemed eligible;

--participants must be both financially eligible and at nutritional risk;

--WIC child services available only up to age 5; but certain booster shots are necessary after 5;

--WIC staff may be largely nutritionists and may fail to do proper age appropriate immunization screening if not adequately trained;

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[262] Some have reported that a major immunization barrier is the parents lack of information about disease and that young parents are skeptical about the need for immunization. Zamichow, N. (1992, February 3). Program Set To Immunize Preschoolers. The Los Angeles Times, Metro, part B, p.1. This story reports that Sandy Ross, immunization coordinator for San Diego County, one of six locations targeted by the CDC for special immunization efforts, said that "for most of today's parenting population, they are young and have never seen any of these illnesses .. [i]f you don't see a risk, you don't see a reason to put out the 'effort to prevent the disease."

--chronic understaffing may result in emphasis upon only the nutrition aspects of program and neglect of possible time-consuming health care referrals.

--there is no specific agency guidance on how to carry out referral functions or to track the outcome of referrals.

SUPPLEMENTAL FOOD PROGRAM FOR WOMEN, INFANTS AND YOUNG CHILDREN ("WIC")

Program name and statutory citation	Special Supplemental Food Program for Women, Infants and Young Children 42 USC § 1786 et seq.
General program structure	Grants to local governments, nonprofit health and welfare agencies, -Indian tribes to provide supplement foods and nutrition education. The program "shall serve as an adjunct to good health care, during critical times of growth and development, to prevent the occurrence of health problems ... and improve the health status of these persons."
Specific authorizing provision related to childhood immunizations	Requires states to describe plans for coordinating WIC programs with other programs including "immunization" and "well child care," "maternal and child health care." Priority funding designation for local health agencies providing or entering into agreements with others to provide "routine pediatric . . . services. 7 CFR 246.5 (d) (1) (i-v).
Authorized appropriations level Fiscal Year 1992	Such sums
Fiscal 1993 appropriations level	$2.6 billion
Specific authorized funding earmark for immunizations	No'
Specific appropriations earmark for immunizations	No
Administering agency	USDA coordinating with HHS
Federal regulations	42 CFR 235, 246
Agency guidance	Yes

22. Child Care Proarams

a: Child Care and Development Block Grant

This program, enacted in 1990, authorizes the Secretary to make formula grants to the states for the purposes of increasing the availability, affordability, and quality of child care services for low-income families.[263] The statute requires states to reserve 25% of grant funds for before and after school care and to improve early childhood developmental. services.[264] Children less than 13 years of age whose families meet income requirements are eligible to participate.[265]

This program does not address provision of health services as part of the child care program but does require that funded care givers comply with all state licensing requirements and health and safety requirements, specifically immunization requirements.[266] States may use grant funds to monitor and improve provider compliance with regulatory standards. States may also use funds to provide training and technical assistance to providers. Both of these activities could promote immunization rates. To the extent that states differ in immunization requirements for child care providers, this program may vary in its ability to promote immunization.

The statute permits states to impose more stringent licensing and regulatory standards on providers funded by this program.[267] Agency guidance reiterates the statutory requirements that grantees be in compliance with state health and safety standards, including immunization schedules, but does not elaborate or make any reference to grantee use of CDC immunization schedule in place of the state schedule. However, when adopting final regulations governing this program, the ACF addressed the problem of immunization status at some length, particularly with regard to the measles epidemic, and stated that grantees should develop contacts

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[263] 42 USC § 9858(1992).

[264] 42 USC § 9858(c)(3)(C).

[265] 42 USC § 9858n(4).

[266] All states require the following immunizations for day care and Head Start children: diphtheria, tetanus, measles, mumps, and rubella. All states but Kentucky and Maine require Pertussis immunization for day care and Head Start children. Most states require Haemophilus influenzae b vaccine for day care and Head State children. CDC, PHS, HHS, State Immunization Requirements 1991-1992.

[267] 42 USC § 9858c(2)(E).

with local health agencies to obtain information on communicable diseases and immunization schedules.[268] The ACF further stated that grantees should be aware that they may use block grant funds to pay for immunization outreach efforts and to pay for the costs associated with immunization of children by public health nurses.[269]

b. Title XX--Block Grants To States For Social Services

This capped entitlement program provides grants to states to furnish services to promote the following goals among low-income individuals and families achieve economic self-sufficiency, reduction of child abuse and neglect, and preventing unnecessary institutional care but securing appropriate institutional care.[270]

Title XX funds cannot be used for medical care except family planning, certain detoxification and rehabilitation services.[271] State reporting data indicate that most Title XX funds are spent on day care for children, home-based services, protective services for children, adoption services, social support services, and special services for the disabled." These services overlap in many respects with state Title IV-B and E services.

The statute permits states to transfer up to 10% of Title XX funds to the preventive health and health services and maternal and child health block grants." States with serious immunization problems could make use of this transfer authorization. Consideration should be given to amendment of this statute to allow for provision of immunization services as such services would

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[268] 57 Fed. Reg. 34352, 34411(August 4, 1992).

[269] Ibid.

[270] 42 USC § 1397(1992). Enacted in 1974 as an entitlement program to fund state social services programs, 1981 amendments established a block grant format and eliminated mandates regarding priority recipients and provisions related to targeting funded services to low-income individuals and families. Green Book p.742.

[271] 42 USC § 1397d(a)(4)(1992).

[272] Staff of House Comm. On Ways and Means, 102d Cong., 2d Sess., Overview of Entitlement Programs: 1992 Green Book 833 (Comm. Print 1992).

[273] 42 USC § 1397a(d)(1992).

directly fall within the ambit of one of the statute's goals--preventing and remedying child neglect. There are no substantive regulations for this program; general block grant fund regulations apply, 45 CFR Part 96. There is no agency guidance.

CHILD CARE AND DEVELOPMENT BLOCK GRANT

Program name and statutory citation	Child Care and Development Block Grant 42 USC § 9858
General program structure	Formula grants to states to increase the availability, affordability, and quality of child care services for low-income families with one parent working or attending a job training or educational program. Funding is available for early childhood development services.
Specific authorizing provision related to childhood immunizations	Funded child care providers required to comply with state health and safety laws including immunization
Authorized appropriations level Fiscal Year 1992	$825 million
Fiscal 1992 appropriations level	$825 million
Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations	No
Administering agency	HHS/ACF
Federal regulations	45 CFR Parts 98 and 99
Agency guidance	Yes, ACF Action Transmittal No. CC&DBG/AT 91-2 (6/21/91)

TITLE XX BLOCK GRANTS TO STATES FOR SOCIAL SERVICES

Program name and statutory citation	Block Grants to States for Social Services 42 USC § 1397
General.program structure	Federal assistance to states to encourage services aimed at promoting economic self-sufficiency, preventing or remedying child abuse and neglect, preventing and reducing inappropriate institutional care. Specific prohibition on use of funds for medical care other than family planning, rehabilitation or substance abuse treatment "unless it is an integral but subordinate part of a social service for which grants may be used under this title[.]"
Specific authorizing provision related to childhood immunizations	No
Authorized appropriations level Fiscal Year 1992	$2.8 billion
Fiscal 1992 appropriations level	$2.8 billion
Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations .	No
Administering agency	HHS/ Office of Human Development Services
Federal regulations	45 CFR Part 96
Agency guidance	No

23. Child Welfare Proarams under the Social Security Act

Title IV of the Social Security Act[274] authorizes appropriations to state programs that provide aid to families with dependent children and assist with foster care, adoption assistance services, and a broad range of child welfare services.

a. Title IV-A, Aid to Families with Dependent Children (AFDC)

The AFDC program, administered by the Office of Family Assistance within the Family Support Administration, is an entitlement program that provides cash payments to needy children generally up to age 18 who lack support because at least one parent is dead, disabled, continually absent from the home, or unemployed.[275] The number of AFDC families rose more than 50% from 1971 to 1981. From 1982 to 1991, AFDC enrollment fell and then reached an all-time high in 1991. The program is projected to increase steadily but slowly up through 1997.

All states participate in this program. The states determine need levels, benefit formulas[276] and determine (within federal limits) income and resource limits. States administer or supervise the administration of this program

The federal government funds between 50 to 80 percent of each state's benefit payments and 50 percent of the 'states' administration costs. In 1989, the federal funding outlay for benefit payments was $9.0 billion, roughly 54 percent of each benefit dollar paid out by states. Adjusting benefit payments for

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[274] 42 USC § 601 et seq., Title IV-A.

[275] The Family Support Act of 1988, P.L. 100-485, amended Title IV-A to mandate that all states establish AFDC-UP progrmas for two-parent families in which the primary wage earner is unemployed. This provision was effective October 1, 1990 and will be repealed September 30, 1998. In 1989, 22 states did not have such a program. Staff of U.S. House of Representatives Committee on Ways and Means, 101st Cong., 2d Sess., Overview of Entitlement Programs: 1990 Green Book 622 (Comm. Print 1990). This amendment is estimated to bring about 65,000 new families onto AFDC roles each month even if states choose to offer AFDC benefits only 6 months out of 12; if states choose to offer 12 months of benefits, about 105,000 families will be added each month. Id. As a result of this amendment, Federal costs for AFDC payments in 1993 are expected to increase from $420 million to $520 million. Id.

[276] In January, 1992, AFDC benefit payments for a family of three with no countable income ranged from a low of $192 in Mississippi to a high of $924 in Alaska. 1992 Committee Print.

inflation, there was a 39 percent median decline in benefit levels from 1975 to 1990.

There is nothing in the AFDC legislation or the regulations addressing health care, although AFDC payments could clearly be used by recipients to purchase care. AFDC eligibility automatically entitles recipients to Medicaid participation and states must provide transitional Medicaid benefits to those who will lose AFDC eligibility as a result of increased income/resource levels.

Title IV-A permits states to operate an Emergency Assistance program (to needy families whether or not AFDC eligible) or to include in their AFDC needs assessment procedures, a category for "special needs" of AFDC recipients. The federal government provides a 50 percent match for the Special Needs program and a 50 percent match for a period not in excess of 30 days in any 12 month under the Emergency Assistance program. As of 1990, 32 states elected of operate an Emergency Assistance program. Payments under the AFDC Emergency Assistance program increased from a total of $14 in 1970 to $348 million in 1991. Although most emergency situations related to alleviating the effects of natural disasters or housing/utility problems, states have specified other qualifying expenses including health care. Of the 34 states electing to cover Special Needs, none reported health care costs as included in this assessment.

b. AFDC/Child Care Services

The AFDC program requires that states guarantee child care if it is decided that child care is necessary for an AFDC individual's employment or participation in education or training programs, or if an individual would be at risk for AFDC eligibility without employment. Transitional child care is also mandated for those soon to lose AFDC eligibility.

AFDC families participating in employment, education or training are eligible to receive child care and other supportive services including day care for children under 3 years of age.[277] While this program does not itself address provision of health services, Title IV-A agencies providing child care are required to be in compliance with state health and safety requirements.[278] To the extent that such programs comply with these requirements,

[277] 42 USC § 602, 603 and 1302(1992).

[278] 45 CFR § 255.5(a)(1992).

children receiving these services should be assessed and at least referred for appropriate immunization. The regulations are not clear as to whether the Title IV-A agencies may directly provide or pay for the provision of necessary immunization. There is no specific agency guidance, however, addressing medical care or immunizations for the Title IV-A programs.

c. Adoption Assistant and Foster Care

The Title IV-B program authorizes funding for state child welfare services. The term "child welfare services" is broadly defined as "public social services which are directed toward the accomplishment of the following purposes: (a) preventing or remedying or assisting the in solution of problems which may result in, the neglect, abuse, exploitation or delinquency of children; (b) protecting and promoting the welfare of all children, including handicapped, homeless, dependent, or neglected children . . . ;(f) assuring adequate care of children away from their homes . . ."[279] Title IV-B does not require that families meet' AFDC eligibility requirements to be eligible for these services. Title IV-B funds are distributed to states based upon the population under 21 and per capita income. Title IV-B funds appear to be available for medical care but there is no guidance on this point. The program requires that case plans for each recipient include health and education records. To this extent, immunization needs may assessed and deficiencies detected.

The Title IV-E program authorizes funding for state foster care and adoption services. To obtain foster care services, the child would have to have been eligible for AFDC if still in the parental home. Adoption services are available without regard to AFDC eligibility. Title IV-E funds are an open-ended matching entitlement to the states for maintenance payments for eligible children in foster care family homes, private non-profit child care facilities, or public child care institutions. These payments may be used for the costs of food, shelter, clothing, daily supervision, school supplies, general incidentals, insurance and reasonable travel but there is no mention of medical or health services, As under Title IV-B, there is a requirement that recipient case plans include health and education records but there is no agency guidance that addresses medical care for these recipients.

[279] 42 USC § 625(a)(1)(1992).

Children served by Title IV-B and Title IV-E programs are eligible for Medicaid participation.[280]

d. Supplemental Security Income Program ("SSI")

The SSI program is a means-tested, federally administered income assistance program. Begun in 1974, SSI provides monthly cash payments to eligible recipients in accordance with uniform, national eligibility standards. To qualify for SSI, a person must be at least 65 years of age, blind, or disabled. A child under 18 years of age with a disability of severity comparable to an eligible adult may be eligible for SSI benefits. The number of children eligible for SSI has grown from 105,000 in 1975 to 263,000 in 1988. The estimated federal cost of the SSI program for 1991 was about $14.5 million. In most states, SSI eligibles are also eligible for Medicaid; 13 states, however, impose more restrictive eligibility requirements for Medicaid participation. A study completed in 1979 showed that 15 percent of SSI children were in foster care and over half of these children were mentally retarded.

Title IV of the Social Security Act[281] authorizes appropriations to state programs that provide aid to families with dependent children and assist with foster care, adoption assistance services, and a broad range of child welfare services.

[280] See 45 CFR § 1356.40(b)(3) (Title IV-E); See 42 USC § 672(h).

[281] 42 USC § 601 et seq., Title IV-A.

CHILD CARE PROGRAMS UNDER TITLE IV-A OF' THE SOCIAL SECURITY ACT

Program name and statutory citation	Title IV-A of the Social Security Act a. Child Care for AFDC Recipients 42 USC § 602, 603, 1302 b. Transitional Child Care (TCC) Assistance 42 USC § 602, 603, 1302 c. At-Risk Child Care Program 42 USC § 602(i) d. Child Care Licensing and Improvement Grants 42 USC § 602g
General program structure	These four Title IV-A entitlement programs fund child care services for AFDC families. Each program targets the following sub-group of AFDC recipients: --AFDC families in an approved work or training program; --families in transition from AFDC; --families at risk for becoming AFDC eligible; --grants to states to improve child care licensing standards provider training.
Specific authorizing provision related to immunizations	a. No b. No c. No d. No
Authorized appropriations level Fiscal Year 1992	a. Such sums b. Such sums c. $300 million d. None

Fiscal 1992 appropriations level	**a.** $12.4 billion **b.** $69.9 billion **c.** $383.75 million **d.** None
Specific authorized funding earmark for immunizations	**a.** No **b.** No **c.** No **d.** No
Specific appropriations earmark for immunizations	**a.** No **b.** No **c.** No **d.** No
Administering agency	HHS/ACF
Federal regulations	**a.** 45 CFR Part 255 **c.** 45 CFR Part 256 **d.** 45 CFR Part 257 None
Agency guidance	Nothing related to **immunization.**

24. Child Nutrition

There are 8 statutory programs administered by the Department of Agriculture that serve populations of low-income' and other children and adults who may be deficient in their immunization status. Because these programs are oriented primarily, if not exclusively, toward the provision of food and nutrition services, their application to immunization services and education appears marginal at best. Accordingly, the description of these food programs is combined in this memorandum. The USDA's Child and Adult Food Care Program, however, appears to offer greater potential for the Department to promote immunization. It is described below at some length.

a. Child and Adult Food Care Program

The Child and Adult Care Food Program (CACFP) has the potential to promote vaccination of infants and children in nearly all types of day care. Program officials recognize this potential. However, realization of this potential depends on the capacity of CACFP to a) reach as many children as possible and b) concern itself with their immunization.

More than 6 million children, including more than 2 million infants and children under age three, spend at least part of their day in out-of-home child care.[282] Children under age 6 are at risk of inadequate immunization against preventable diseases because they are too young to encounter universal school-entry vaccination requirements. The risk is greater for children from low-income families with poor access to health services. Because of their close and continuing relationship with children and parents, child care programs can play a primary or backup role in assessing the immunization status of children in their care, educating families about the importance of immunization and referring them to sources of immunization both for children in care and siblings.

CACFP can be an effective vehicle for promoting childhood immunization for two reasons. First, it has the potential to reach large numbers of young children because it authorizes federal assistance for food services in all types of child care except for-profit programs.

[282] Adams, G.C., Who Knows How Safe? The Status of State Efforts to Ensure Quality Child Care (Childrens' Defense Fund, Washington, D.C. 1990).

Second, eligibility for CACFP benefits constitutes a strong incentive for providers, especially those caring for low-income children, to concern themselves with the immunization status of children in their care.[283] The statute[284] and regulations[285] require providers, as a condition of participation, to be in compliance with applicable Federal, state and/or governmental licensing or approval requirements, including, by implication, those pertaining to immunization.

The CACFP program is an entitlement, authorizing grants to states on the basis of meals served to children, and commodity donations.[286] States reimburse eligible child care programs for the costs of their food services. The statute contemplates benefits for children in virtually all types of non-residential public and nonprofit private programs. Eligible organizations include but are not limited to child care centers, Head Start, settlement houses, neighborhood centers, home-based programs**' and their sponsoring organizations, before- and after-school programs (for children up to age 13); also programs for migrant workers' children (up to age 16) and programs caring for handicapped children, primarily those up to age 19.[288]

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[283] Child care programs are reimbursed at higher rates for meals served to children from low income families that qualify for reduced-price and free meals than for meals for children from higher income families. (42 USC § 1766(f) (1990); see note 12 for eligibility of children).

[284] 42 USC § 1766(a)(1)(1992).

[285] 7 CFR § 226.8(a) (1991).

[286] 42 USC § 1766(h)(1)(A),(n)(1992).

[287] "Home-based care" occurs in the residence of the provider; in this analysis, the term is used for both "family" and "group" day care homes referenced in the statute. Some states distinguish, for purposes of regulation, between "group family day care homes," which care for comparatively larger numbers of children, and smaller "day care homes." "Day care homes" as used in CACFP regulations refers to licensed or approved day care in a provider's residence and under the auspices of a sponsoring organization. 7 CFR § 226.2 (1990).

[288] 42 USC § 1766(a)(1)(1992); 7 CFR § 226.2(1990).

Also eligible are providers, including for-profit entities, whose care of children is subsidized by the title XX Social Services Block Grant to states,[289] and organizations participating in two state-wide CACFP demonstrations by certain for-profit providers.[290]

The CACFP statute also contemplates special efforts by states and providers of child-care services, assisted by the Secretary of Agriculture, to make food services available to low-income children. These children are entitled to CACFP meals free or at reduced prices, if they are enrolled in a'child care program that chooses to participate in the program and meets its standards, and if their families meet income standards[291] of the National School Lunch Act[292] and the Child Nutrition Act.[293]

As a condition of participating in CACFP, states must act affirmatively to expand the availability of CACFP benefits.[294] The statutory minimum for compliance with the mandate is that a state must annually notify eligible, non-participating .child-care provider in its jurisdiction of the availability of CACFP, participation requirements and application procedures. The notice must go to regulated providers or those qualifying as recipients of title XX funds.[295] The Secretary is required to assist states in developing plans for satisfying their statutory duty of expansion.[296]

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289 42 USC § 1397 et seq. (1991).

290 The statute authorizes two state-wide demonstration projects in which nonresidential private, for-profit day care providers may participate in CACFP if, inter alia, 25 percent of children in their care qualify for free or reduced price meals. (42 USC § 1766(q) (1992). See note 12 for eligibility of children.)

291 42 USC § 1766(c)(4) (1992).

292 42 USC § 1751 et seq. (1992).

293 42 USC § 1771 et seq. (1992) Children whose family incomes do not exceed 185% of federal poverty guidelines, adjusted annually for inflation, are eligible for reduced price meals. Children whose family incomes do not exceed 130% of federal poverty guidelines are eligible for.(42 USC § 1758(b) (1) (A),(B); 42 USC § 1773(e)(1)(1992).

294 42 USC § 1766(k)(l) (1992).

295 Ibid.

296 Ibid.

The states and the Secretary are both required to train sponsors of home-based- care and provide them with technical assistance on methods of expanding the program to include more low income children.[297] Also, the Secretary must conduct demonstration projects on minimizing or eliminating barriers to participation by family and group day care homes that primarily serve low-income children or are located in low-income areas.[298]

More generally, as a condition of participating in the program, states must provide training and technical assistance to child care programs to "facilitate... [their] effective operation" of the food program.[299]

As of March 1, 1990, slightly more than a third of the 6 million American children in child care, or about 2.5 million, were in programs receiving CACFP assistance.[300] The capacity of CACFP to reach low-income children is limited to the extent that child-care programs for Aid to Families with Dependent Children (AFDC)[301] participants and those subsidized by the new Child Care and Development Block Grant[302] are for-profit entities (other than home-based programs). Otherwise, the reach of the program depends on the willingness of child-care providers to participate and on the commitment of the Secretary, the states, and providers to program expansion.

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[297] 42 USC § 1766(a)(3) (1992).

[298] 42 USC § 1776(k)(3) (1992).

[299] 42 USC § 1776(k)(l) (1992).

[300] Food and Nutrition Service, Department of Agriculture. The total reflects average daily attendance of children in CACFP-qualified programs as follows: child care centers, 1.3 million; home-based care, 696,011; title XX providers, 76,051; before- and after-school care, 110,724;. Head Start, 296,5522.

[301] 42 USC § 602(g)(l),(i) (1992). The three "title IV-A" child care programs for children of a) AFDC education and job-training program participants, b) former AFDC recipients in the first year they earn enough to not qualify for basic benefits, c) families at risk of becoming AFDC recipients, are described in a separate analysis. All may arrange for day care through for child care through, inter alia, for profit providers. (7 CFR §§ 255, 256; 56 Fed.Reg. 29054 (1991) to be codified at 7 CFR §§ 255-257 (proposed June 25, 1991).

[302] 42 USC 9859 (1992). States receiving block grants must fund child-care services at sites chosen by parents of eligible children. For-profit entities are not excluded from the program.

Program appropriations indicate growth, rising from $599.8 million in fiscal 1988 to $1.2 billion in fiscal 1992.[303] Much of the recent growth has been in middle-class home care sites; one leading analyst suggests that the higher incentives for serving low-income children have created good rates of participation by organizations serving these children, but that there are reasons to believe some centers may still be unfamiliar with CACFP.[304] States are required to submit copies of letters with which they notify eligible, nonparticipating providers of the program.

The Secretary could, by regulation, define more broadly the states' affirmative duty to expand the program, to include investigating the degree to which notice letters may miss eligible providers, especially those serving low-income children. Smaller home-based programs would not receive a letter if, as is often the case, they are exempt from state regulation and thus are not readily identifiable through state records. "Notice" could be defined more broadly to include public information or other strategies in addition to a letter.

In substance and in implementation, the state and local licensing/ approval laws referenced by the statute do not uniformly guarantee that children in out-of-home care are adequately immunized. As of 1990, 13 states did not require children in home-based care to have age-appropriate immunization against polio, measles, rubella, mumps, diphtheria, tetanus and pertussis.[305] Twenty-two states exempted home-based programs caring for five or fewer unrelated children, and 36 states exempted such homes caring for three or fewer children from mandatory regulation under a system that required inspections.[306] Some 14 states exempted at least certain types of programs operated by religious institutions from such regulations.[307]

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[303] U.S. House of Representatives, Committee on Agriculture, Subcommittee on Domestic Marketing, Consumer Relations and Nutrition.

[304] Personal communication, July 28, 1992, Robert Greenstein, executive director, Center on Budget and Policy Priorities, Washington, D.C.

[305] Adams, G.C., note 1, at 18.

[306] Ibid., at 9.

[307] Ibid. at 12.

Thirty-two states did not require children 18 months and older in licensed day care centers to have received the Hib vaccine.[308]

If immunization standards are adequate, their effectiveness may nevertheless be undermined in enforcement. More than a third of the states have reported that staff shortages curtail site visits to monitor compliance with their laws. While HHS has found frequent monitoring to be the best method of assuring compliance with licensing or approval standards, it has estimated that fewer than half of the home-based care programs subject to regulatory inspections were actually inspected in 1988. Just 21 states visit these programs each year. Seven states only inspect home-care programs about which there have been complaints. A number of states approve home-based programs on the basis of self-certification and do not independently verify compliance with their standards.[309]

These shortfalls in current licensing/approval laws and enforcement constitute a gap that CACFP could help fill by reaching, through child care, families that might otherwise be poorly informed about immunization.

b. Food Service Programs

The following programs administered by the USDA generally serve low-income children up to age 18 in schools and other community program locations. None of them, however, have significant potential for addressing immunization.

Summer Food Service Proaram For Children

This program primarily funds food service to children under 18 enrolled in summer youth programs in low-income communities. There are no record-keeping or family contact requirements.

Special Milk Program for Children

One of the statutory purposes of the Child Nutrition Act, which authorizes this program, is to "safeguard the health and well-being of the nation's children."[310] The statute and regulations stress increased milk consumption to the exclusion of other activities, however, one percent of funds may be reserved by agencies "special developmental projects."[311] States may also

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308 Ibid. at 18.

309 Ibid. at 46.

310 7 USC § 1771 (1991).

311 7 CFR § 215.6(a).

impose requirements on funded agencies that are not inconsistent with the purposes of the Act.[312]

School Lunch Proaram

As with the Special Milk Program, even though the authorizing statute sets out child "health and well-being" as a goal, the exclusive focus of this program is financing nutritious school lunch services for low-income children under 21. There are no statutory or regulatory provisions that could be interpreted to authorize immunization-related activities.

School Breakfast Proaram

The program provides free breakfasts to low-income children and infants. There are no statutory or regulatory provisions that would directly support immunization-related activities, except that infants are also served by the program[313] and mothers or other infant care-takers could be exposed to educational efforts undertaken at the school sites.

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[312] 7 CFR § 215.8(e).

[313] 7 CFR § 220.8(b).

SCHOOL LUNCH PROGRAM

Program name and statutory citation	National School Lunch Program 7 USC § 1751 et seq.
General program structure	Food service grants to states to assist in meeting costs of school lunch services; eligible schools are public and non-profit private schools including high schools, also public, nonprofit private residential child care institutions; children through high school, or disabled individuals under 21 enrolled in eligible residential institutions are eligible for food service.
Specific authorizing provisions related to childhood immunizations	No
Authorized appropriations level Fiscal Year 1992	**Such sums** as may be necessary.
Fiscal 1992 appropriations level	$4.2 billion
Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations	No.
Administering agency	Food and Nutrition Service, Department of Agriculture.
Federal regulations	7 CFR § 210
Agency guidance	No

SCHOOL BREAKFAST PROGRAM

Program name and statutory citation	School Breakfast Program 42 USC § 1773
General program structure	Grant-in-aid and commodity donations program authorizing payments and donations to states to subsidize nonprofit breakfast services for children at schools and other sites, with priority first for schools in economically distressed areas; second, schools to which students must travel long distances; third, schools with a special need to improve the nutrition of children of working mothers and children from low-income families; amount of federal assistance determined by total number of meals served multiplied by federal reimbursement rate; eligible institutions are a) public and nonprofit schools through high school, including preschool programs located in such schools and b) public or nonprofit private licensed residential child-care facilities, including group homes, facilities for unwed mothers and infants, temporary shelters for children and runaways, juvenile detention centers and institutions for chronically ill or disabled children.
Specific authorizing provisions related to childhood immunizations	No
Authorized appropriations level Fiscal Year 1992	Such sums as may be necessary for food service and administration; $5 million for program start-up costs
Fiscal 1992 appropriations level	$744.8 million

Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations	No
Administering agency	Food and Nutrition Service, Department of Agriculture
Federal regulations	7 CFR § 220
Agency guidance	No

SPECIAL MILK PROGRAM FOR CHILDREN

Program name and statutory citation	Special Milk Program for Children 42 USC § 1772
General program structure	Food service grants to states, for subsidized and free milk served to children and adolescents in schools and institutions that do not participate in school lunch, child and adult care food program, or other federal child nutrition programs. Eligible institutions are public and nonprofit private schools through high school, including preschool programs and public, nonprofit private child-care facilities, including group homes, facilities for unwed mothers and infants, temporary shelters for children and runaways, juvenile detention centers and institutions for chronically ill children or disabled children.
Specific authorizing provisions related to childhood immunizations	No
Authorized appropriations level Fiscal Year 1992	Such sums as may be necessary
Fiscal 1992 appropriations level	$23 million
Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations	No.
Administering agency	Food and Nutrition Service, Department of Agriculture
Federal regulations	7 CFR § 215
Agency guidance	Yes

SUMMER FOOD SERVICE PROGRAM FOR CHILDREN

Program name and statutory citation	Summer Food Service Program For Children 42 USC § 1761
General program structure	Food service grants to states to subsidize non-profit food service for children in May through September and at other vacation times; service provided by schools and other eligible entities; service restricted to economically distressed areas. Children up to age 19 may be served; older individuals in facilities for the handicapped may be served.
Specific authorizing provisions related to childhood immunizations	No
Authorized appropriations level Fiscal Year 1992	Such sums as may be necessary
Fiscal 1992 appropriations level	$189.3 million
Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations	No
Administering agency	Food and Nutrition Service, Department of Agriculture
Federal regulations	7 CFR § 225
Agency guidance	No

CHILD AND ADULT CARE *FOOD* PROGRAM

Program name and statutory citation	Child and Adult Care Food Program 42 USC § 1766
General program structure	a. Food service grant-in-aid and commodity donations program providing payments and donations to states to support meals and snacks for children in eligible, nonresidential child-care programs; amount of federal assistance determined by the total number of meals served, multiplied by allowable per-meal rates for full-price and, for low-income children, reduced price and free meals, with additional funds for administrative expenses. b. Children in qualifying child-care programs are entitled to subsidized meals. Eligible programs include public or nonprofit, nonresidential child care centers, Head Start, home-based programs (through nonprofit or public sponsoring organizations), programs serving children of migrant workers and children with handicaps.
Specific authorizing provisions related to childhood immunizations	By implication only. Statute requires child-care programs or sponsors to be licensed or approved under applicable Federal, state or local standards including, by implication, requirements that a child be immunized to enter organized child care.
Authorized appropriations level Fiscal Year 1992	Such sums as may be necessary
Fiscal 1992 appropriations level	$1.2 billion (includes $38 million in donated commodities)
Specific authorized funding earmark for immunizations	No

Specific appropriations earmark for immunizations	No.
Administering agency	Food and Nutrition Service, Department of Agriculture
Federal regulations	7 CFR § 226
Agency guidance	No

25. Expanded Food and Nutrition Education Program of the Cooperative Extension Service (EFNEP)

Unlike the above-described food service programs which are not designed for immunization-related activities, the EFNEP program has potential for sustained immunization-related efforts.

The Cooperative Extension Service (CES) has a long history as a federal-state-local network for diffusing applied-research information about agricultural and home economic subjects to & rural and small town families and, increasingly, a low-income urban audience. The network runs from CES offices in state land-grant universities, to CES offices in counties to individuals/families, directly through local media and community meetings.

CES programs focus on (1) Educational Base Programs such as 4-H & Youth Development which specifically address nutrition and health education; (2) National Initiatives which address current social problems. Agendas for CES activities are to be determined by the needs of the community to be served.

One EFNEP National Initiative is "Plight of Young Children: Prenatal to Age Five"[314] addresses a range of health, nutritional and educational problems encountered by low-income families and specifically mentions immunization problems in this population. The paper proposes that CES emphasis reaching this population, particularly WIC and Food Stamp participants, and providing education and referral for health and immunization services.

[314] Dunn, C. and Myers-Walls, J. (May 21, 1991). "The Plight of American Children: Prenatal to Age Five." U.S. Dept. of Agriculture, Home Economics and Human Nutrition.

COOPERATIVE EXTENSION SERVICE
EXPANDED FOOD AND NUTRITION EDUCATION PROGRAM

Program name and statutory citation	a. Cooperative Extension Service 7 USC § 341 et seq. b. National Food and Human Nutrition Research and Extension Program ("expanded food and nutrition education program," EFNEP) 7 USC § 343(d), 3175
General program structure	a. Grants to extension offices in state land-grant universities to assist them in meeting the costs of state, county and local public information, education and demonstration programs focused on, inter alia home economics; b. Grants to extension offices as above, for nutrition and consumer education programs for low-income persons, Food Stamps, WIC (Supplemental Food Program for Women, Infants and Children) other food aid.
Specific authorizing provisions related to childhood immunizations	a., b. By implication only. "Home economics" is broadly construed by the service to include program emphases ("national initiatives") on the well-being, including the health status, of young children from low-income, poorly-educated families, and "at risk" youth. EFNEP is broadly construed to include parent education as well as nutrition and resource management information.
Authorized appropriations level Fiscal Year 1992	a. Such sums as may be necessary b. $68 million
Fiscal 1992 appropriations level	a. $414 million b. $60 million
Specific authorized funding earmark for immunizations	No

Specific appropriations earmark for immunizations	No
Administering agency	Extension Service, Department of Agriculture
Federal regulations	No
Agency guidance	Yes

26. Education Programs

a. Even Start Family Literacy Program

This program assists parents in becoming "full partners in the education of their children" and "children in reaching their full potential as learners" by "integrating early childhood education and adult education for parents into a unified program."[315] There is a 3% percent funding set aside for programs serving migrant children conducted by the Office of Migrant Education. All States, the District of Columbia and the Commonwealth of Puerto Rico are eligible to receive federal funds under this program to be made available to local educational agencies (LEAs) applying in collaboration with a community-based organization, public agency, institution of higher learning, or other non-profit organization.[316]

One of the funding priorities is that applicants demonstrate that their proposed service area include a large number of children and adults who exhibit high levels of "poverty, illiteracy, unemployment, limited English proficiency, or other need-related indicators."[317] Another priority is that applicants demonstrate cooperation and coordination of a wide variety of "relevant service providers" for all phases of the program.[318] Grants may be awarded for up to 4 years.

Funded programs are required to screen and prepare parents and children for participation in the program through vesting, referral to necessary counseling and related services.[319] In 1991, the statute was amended to include within required program elements "developmental and support services."[320] The broad language of this statutory provision could be interpreted to include assistance in obtaining health care, particularly immunization, and could authorize direct provision of such services. Eligible participants are parents in an adult basic education program and children from birth to age 7.[321]

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[315] 20 U.S.C. § 2741, 2744(a).

[316] 20 U.S.C. § 2742(d)(l).

[317] 20 U.S.C. § 2747(a)(l)(B) (1992).

[318] 20 U.S.C. § 2747(a)(l)(C) (1992).

[319] 20 U.S.C. § 2744(b)(2) (1992).

[320] Pub. L. No. 102-73, Title III, § 303(d), 105 Stat. 352; 20 U.S.C. § 2744(b)(2) (1992).

[321] 20 U.S.C. § 2745(a) (1992).

Eligibility continues until all family members become ineligible for participation.[322]

This program clearly has potential for improving immunization rates among children and adults. It targets high-risk infants and children up to age 7 and adults who have long-term eligibility for this service. The program requires LEAS to collaborate and coordinate a broad range of support services for this population that could readily include health care and health care education. On-site vaccinations could be provided as part of the Even Start program. At a minimum, this program would appear to provide for participant referral to other Federal programs such as WIC, AFDC, Medicaid.

The agency is currently preparing a Q & A guidance format for grantees.

b. Migrant Education

This program provides formula grants to state educational agencies (SAEs) to be used for supplementary education and support services provided by local educational agencies (LEAs) to meet the special education needs of migrant youth. Program funds may be used for a wide variety of educational and support services including health services.[323] Grantees must coordinate with other federal programs including Head Start and the Migrant Health Program.[324] The Secretary is authorized to enter into contracts with SEAs to maintain and operate a migrant student record system that provides for transfer of such records among SAEs and LAEs.[325] These system is to include academic, health, and other education records and management information on migrant children that is to be available upon request to states and other agencies. There is no requirement, however, that immunization information be included in this record system.

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[322] 20 U.S.C. § 2745(b) (1992).

[323] Migrant Education Program Policy Manual 1991, p. 81;

[324] 20 U.S.C. § 2782(a)(2).

[325] 20 U.S.C. § 2783(a)(2)(A).

The program serves migrant children up to 21 years of age but focuses on children from 3 to 21 years old.[326] LEAS may in certain circumstances run day care for migrant children age two or younger.[327]

A Department of Education spokesperson estimates that approximately 250,000 children are served by this program at about 10,000 sites, mostly rural schools.

There is no data indicating how many children would be eligible. The absence of this critical data affects program funding, which is based on number of migrant children in a state.

The Migrant Education program has the necessary authority to address immunization of migrant children. It appears that vaccinations could be provided on-site at migrant schools for all children in the family. Moreover, the record system is an important source of health information that could track the immunization needs of this highly mobile population. We would recommend that the agency guidance be revised to require specific recording of immunization data and to have the data base incorporate CDC immunization standards into each child's records so that status could be readily assessed. In addition, the regulations should be revised to specifically provide that program funds may be expended for immunization services either directly or by contract.

c. Education Of Individuals With Disabilities

These four programs serve sub-groups of children with disabilities (Indian children, preschoolers, infants and toddlers, birth through eight years). The purpose of each program is to provide grants to states to assist them in meeting the special educational and developmental needs of this population so as to ensure to the extent possible that these children receive the full benefits of public education that are available to their peers. A central feature of these programs is that grantees are required to prepare individual education plan (IEP) for eligible children that is takes into account each child's specific needs. There is no agency guidance addressing medical care needs.

Where the programs provide for "related services," this term has been statutorily defined as including "medical services, except that such medical services shall be for diagnostic and evaluation purposes only as may be required to assist a child

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[326] 34 C.F.R. § 201.3(b)(3)(1); 20 U.S.C. § 2781(b).

[327] 34 C.F.R. § 201.

with a disability to benefit from special education, and include the early identification and assessment of disabling conditions in children. "[328] Although this definition appears to preclude direct provision of immunization services, "related services" also includes "developmental, corrective and other supportive services"[329] which clearly could encompass provision of referral and health care counseling to parents of these children.

d. Education for Homeless Children and Youth

This program provides grants to states to help ensure that homeless children and youth have access to public education by providing activities for and services to this population that enable them to enroll in, attend, and achieve success in school. Grantees are specifically authorized to address barriers to enrollment such as immunization problems.[330] Record keeping requirements specifically include immunization records.[331]

Coordination of and referral to other services available to this population is also required and specifically mentions health care services.[332] If there are surplus funds, non-homeless children and youth may receive program services

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[328] 20 U.S.C. § 1401(a)(17).

[329] Id.

[330] 42 U.S.C. § 11432(e)(1)(G)(ii)(I).

[331] 42 U.S.C. § 11432((e)(6).

[332] 42 U.S.C. § 11432(e)(8)(B).

e. Indian Education .

This program provides formula grants to local educational agencies (LEAs) that have enrolled at least 10 Indian children and schools operated by the Bureau of Indian Affairs (BIA).[333] Funds shall be used by grantees to improve the planning and development of programs specifically designed to meet the special educational or culturally related academic needs of Indian children. The program does not address medical care needs but 90 percent of the grants are awarded to state public schools which must comply with state health and safety standards. All states require immunizations of school age children although the specific immunization schedules may differ. The BIA-administered schools must comply with the immunization standards set by the Indian Health Service (see discussion in Chapter 13). The BIA recently suggested that the IHS provisiohs be amended to require the IHS to immunize all students enrolled in BIA schools.

[333] 25 USC § 2601 (1992).

ASSISTANCE FOR EDUCATION OF INDIVIDUALS WITH **DISABILITIES**

Program name and statutory citation	Education of Individuals with Disabilities (Individuals with Disabilities Education Act, IDEA) 20 USC § 1400 et seq. a. grants to states 20 USC § 1411 et seq.; b. preschool grants 20 USC § 1419; C. early education of children with disabilities 20 USC § 1423; d. infants and toddlers with disabilities 20 USC § 1471 et seq

General program structure	As a condition of receiving funds for IDEA programs for children with disabilities states must, inter alia, provide for each disabled child an individualized education program (IEP), education and education-related services specified by the IEP, and annual review of the IEP. a. formula grants to states (and to Department of Interior, for use for children with disabilities in Indian reservations), to assist them in financing compensatory education and education-related services for children with disabilities ages 6-17, children ages 3-5 if a state serves this age group and individuals ages 18-21 under certain circumstances; b. formula grants to states, for services to preschool children, ages 3-5; c. early education project grants to states to expand and improve early intervention and special education, through research and demonstrations and outreach for children with disabilities from birth through age 8. d. formula grants to develop and implement programs of early intervention services for handicapped infants and toddlers and their families
Specific authorizing provisions related to immunizations	No
Authorized appropriations level Fiscal Year 1992	Such sums as may be necessary.

Fiscal 1992 appropriations level	a. $1.976 billion. b. $320 million. c. $25 million. d. $175 million.
Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations	No
Administering agency	Office of Special Education Programs, Dept of Education.
Federal regulations	a. 34 CFR § 300. b. 34 CFR § 301. c. 34 CFR § 309.1 d. 34 CFR § 303.
Agency guidance	No

PROGRAMS FOR NEGLECTED AND DELINQUENT CHILDREN (CHAPTER I)

Program name and statutory citation	Programs for Neglected or Delinquent Children 20 USC § 2801.
General program structure	Education grant-in-aid program authorizing payments to state agencies responsible for the free public education of 'children in a) residential institutions or day programs for neglected or delinquent children (but not children in foster care) *or* b) adult correctional institutions; payments are for the costs of compensatory educational programs in addition to the basic public education that the state must provide for these children.
Specific authorizing provisions related to childhood immunizations	No
Authorized appropriations level Fiscal Year 1992	Such sums as may be necessary.
Fiscal 1992 appropriations level	$36.1 million
Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations	No.
Administering agency	Office of Elementary and Secondary Education, Department of Education.
Federal regulations	7 CFR Parts 203 & 204.
Agency guidance	Yes

EDUCATION OF CHILDREN WITH DISABILITIES IN STATE-OPERATED OR STATE-SUPPORTED SCHOOLS (CHAPTER I)

Program name and statutory citation	20 USC § 2791
General program structure	Education grant-in-aid program authorizing payments to state educational agencies for financing compensatory programs for children; amount of federal assistance determined by multiplying a state's total number of disabled children by a percentage of its average per-pupil expenditure for education; the total number is of children from birth through age 21 who are in state-funded special programs or programs for disabled children or supported by a state agency responsible for providing them with free public education or, for infants and toddlers, early intervention services; financing is limited to services supplementing basic special education and related services programs; see separate analysis of supplementary services for infants and toddlers, which are authorized separately.
Specific authorizing provisions relating to child-hood immunizations	No
Authorized appropriations level, Fiscal 1992	unspecified level
Fiscal 1992 appropriations level	$143 million
Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations	No

Administering agency	Office of Special Education Programs, Department of Education
Federal regulations	34 CFR Part § 302
Agency guidance	**Yes**

EVEN START

Program name and statutory citation	Even Start Family Literacy Programs 20 USC § 2741 et seq.
General program structure	Project grants to states or eligible agencies to assist in meeting the costs of local instructional programs for young children and their parents, to improve parental involvement in the education of their children, children school performance, and parents' literacy; eligible organizations are school boards or other local educational agencies (LEAs) applying jointly with a community-based organization, a public agency, a college or university or other nonprofit organization, or a community-based or other nonprofit organization applying jointly with a LEA; to be eligible, an organization must have eligible parents and children within its jurisdiction; eligible individuals are children age 1-7 living in an elementary-school attendance areas with large numbers of low-income families (i.e. areas qualifying for educationally-deprived (Chapter I) funding), and adults eligible for-adult education
Specific authorizing provisions related to childhood immunizations	No
Authorized appropriations level Fiscal Year 1992	$100 million
Fiscal 1992 appropriations level	$70 million
Specific authorized funding earmark for immunizations	No

Specific appropriations earmark for immunizations	No
Administering agency	Office of Elementary and Secondary Education, Department of Education
Federal regulations	7 CFR § 212
Agency guidance	In preparation

EDUCATION FOR HOMELESS CHILDREN AND YOUTH

Program name and statutory citation	Education for Homeless Children and Youth 42 USC § 11431 et seq.
General program structure	Grant-in-aid program authorizing payments to states to finance compensatory education for homeless children and to finance activities to link such children and their families with health, social and other non-educational services for which they are eligible; amount of grant to a state is the same proportion of the total appropriation for homeless education as the state's allocation of Chapter I funds for educationally disadvantaged children.
Specific authorizing provisions related to childhood immunizations	State plans are to address: 1) potential barriers to education of homeless children, including those caused by immunization requirements and 2) maintenance of homeless children's school records, including records of immunization. Local education agencies (LEAS) may use program funds for costs of obtaining and transferring records of homeless children, including immunization records, that are required for their enrollment. More generally, immunizations could be financed under authority for funds to be used for services enabling homeless children to attend schools; state plans and LEAs are to provide for referrals of homeless children and families to health and other services.
Authorized appropriations level Fiscal Year 1992	Such sums as may be necessary.
Fiscal 1992 appropriations level	$25 million

Specific authorized funding earmark for immunizations	No, however statute earmarks funds for "related **services"** for homeless children and youth including inter alia, referrals for medical services which might include immunization.
Specific appropriations earmark for immunizations	No.
Administering agency	Office of Elementary and Secondary Education, Department of Education.
Federal regulations	No
Agency guidance	Yes

INDIAN EDUCATION

Program name and statutory citation	Indian Education 20 USC § 2601 et seq.
General program structure	a. Formula grants to boards of education, other local education agencies and Indian-controlled schools to meet the special educational and cultural needs of Indian children. b. Project grants.
Specific authorizing provisions related to childhood immunizations	No
Authorized appropriations level Fiscal Year 1992	a. Such sums as may be necessary; and b. $35 million.
Fiscal 1992 appropriations level	$76.6 million.
Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations	No
Administering agency	Office of Elementary and Secondary Education, Department of Education.
Federal regulations	34 CFR § 250.
Agency guidance	Yes

MIGRANT EDUCATION

Program name and statutory citation	Migrant Education 20 USC § 2781 et seq.
General program structure	a. Education grant-in-aid program authorizing payments to state education agencies (SEAs) to assist in meeting the costs of educational programs for children of migrant workers b. Program grants to SEAs to improve inter- and intra-state coordination of education programs for migratory students by, inter alia, a system for transfers of student records;; amount of federal assistance is a percentage of the full migrant education program appropriation.
Specific authorizing provisions related to childhood immunizations	By implication only; statute authorizes student educational-records transfer program; school records assumed to include documentation of student immunization status.
Authorized appropriations level Fiscal Year 1992	Such sums as may be necessary
Fiscal 1992 appropriations level	$308.3 million
Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations	No.
Administering agency	Office of Elementary and Secondary Education, Department of Education
Federal regulations	a. 7 CFR § 201 b. 7 CFR § 205
Agency guidance	Yes

27. Department of Labor Proarams

a. Job Corp

This program is authorized under Title IV-B of the Job Training Partnership Act (JTPA)[334] and is designed to provide low-income, unemployed youth from 14-21 with a wide range of services who volunteer to live in a 24 hour residential environment for the duration of the program.[335] The services are primarily directed toward overcoming the effects of poverty and assisting these individuals to obtain vocational and employment skills and become responsible citizens. Services, however, include counseling, health care and other support services. Agency guidance states that the health staff at residential centers must screen students within 14 days of arrival, provide necessary immunizations and re-immunizations for the students, and maintain immunization records.[336] The Job Corp standards for immunization must adhere to CDC standards and also be updated periodically.[337]

While this program actually requires direct immunization, the age of this population indicates that many may have received many vaccines as a consequence of elementary or secondary school entry requirements. Some, however, may have never been enrolled in school or attended school without the required immunization. (Are there program data on immunization status of this population?). The emphasis upon provision of health care, particularly vaccines, and broader promotion of life skills could sensitive this population to the need for immunization of themselves and their family members. (Are students admitted to program if they have dependent children?). This program could serve as a model for other agencies who wish to provide direct immunization services to clients.

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[334] 29 USC § 1501 et seq., P. L. No. 97-300, 96 Stat. 1324, enacted in 1982.

[335] Some enrollees attend on a daily basis.

[336] U.S. Dept. of Labor, Employment and Training Administration. (November 1991). Job Corp Policy and Requirements Handbook, Chapter 6, Health Services, p. 11.

[337] Ibid.

b. Job Trainina Partnershin Act

This program constitutes the largest federal job training program in the United States. States receives funds to allocate to local agencies that manage the employment training programs for economically disadvantaged adults and youths.
This program is not residentially-based, focuses on job training and does not provide the type of comprehensive service delivery available under Job Corp. To the extent that preparation for employment would include appropriate immunization, program funds may be available to cover this expense. At a minimum, referral to free immunization programs should be provided. As with Job Corp, there is an opportunity for staff to counsel JTPA participants about the importance of immunizations and this population is likely to be at-risk for lack of primary and preventive health services.

JOB CORPS

Program name and statutory citation	Job Corps (Title IV-B, Job Training Partnership Act) 29 USC § 1691 et seq.
General program structure	Assists economically disadvantaged youths between 14 and 21 obtain educational and vocational skills training within an intensive, residential settings providing a variety of supportive services including health care.
Specific authorizing provisions related to childhood immunizations	By implication only.
Authorized appropriations level Fiscal Year 1992	Such sums as may be necessary.
Fiscal 1992 appropriations level	$955.1 million
Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations	No.
Administering agency	No
Federal regulations	20 CFR § 639
Agency guidance	Yes

JOB TRAINING PARTNERSHIP ACT

Program name and statutory citation	Job Training Partnership Act 29 USC § 1501 *et seq.*
General program structure	Allotments to states to provide job training to economically disadvantaged adults and youths. Supportive services that include health care may be provided to economically disadvantaged farmworkers
Specific authorizing provisions related to childhood immunizations	By implication only.
Authorized appropriations level Fiscal Year 1992	Such sums as may be necessary
Fiscal 1992 appropriations level	IIA $1.7 billion IIB 628.9 million
Specific authorized funding earmark for immunizations	No
Specific appropriations earmark for immunizations	No
Administering agency	Employment and Training Administration, Department of Labor
Federal regulations	20 CFR Parts 626, 629, 630
Agency guidance	Yes

E. DEMONSTRATION CONDUCTED BY TEE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

The United States Department of Health and Human Services funds and administers certain demonstration programs pertaining to the provision of immunization which are demonstration in nature. These demonstrations can be distinguished legally from other types of immunization financing or service delivery efforts in that their legal basis for the program is not found in a specific permanent or time limited piece of authorizing legislation (e.g., Medicaid or community health centers). Instead, the programs are being carried out pursuant to a general Congressional grant of research and demonstration authority to the Department. Using this authority, a particular HHS agency designs a demonstration project which lasts for a fixed term of years and whose funding is included in subsequent annual Congressional appropriations legislation.

Federal agencies conduct demonstrations for several reasons. In some cases the impetus may be the desire to furnish services in addition to (or in a modified version of) services and/or benefits which ordinarily are available to patients under existing authorities. In other cases, an agency may wish to test a new and previously untried approach to health services delivery or limit or modify benefits otherwise available to recipients of federal assistance.

To be consistent with the grant of demonstration authority on which they are based, these efforts are conceived, designed, implemented, and evaluated as formal research projects. In other words, the legal authority which gives rise to these initiatives is predicated on the notion that they will (a) test new ideas and new approaches and (b) incorporate evaluation techniques that permit policy makers to glean important and new information for the purpose of future legislative efforts. Potentially valuable information regarding both positive and negative approaches toward immunizing Americans thus can be obtained from immunization demonstration programs.

The demonstration programs reviewed in this section all involve projects which merit close analysis by federal policy makers concerned with access to immunization. Each tests (either directly or by implication) new approaches to the design of immunization financing and delivery to both children and adults. The projects are:

- an infant mortality reduction initiative known as Healthy Start;
- a pediatric AIDS service demonstration;
- a rural health outreach initiative;

- o an initiative to serve residents of the Pacific Basin;
- o a CDC demonstration to improve the immunization status of WIC and AFDC beneficiaries;
- o a demonstration testing the effects of financial sanctions on the immunization status of AFDC children; and
- o a demonstration to test the effectiveness of broader coverage of vaccines for Medicare beneficiaries.

The first five demonstrations are being carried out under the demonstration authority of the United States Public Health Service.[338] The AFDC initiative is being carried out by the Administration on Children and Families pursuant to a grant of demonstration authority to the Secretary under the Social Security Act.[339] The Medicare demonstration is a Congressionally mandated study being carried out by the Health Care Financing Administration.

28. HEALTHY START

Healthy Start was initiated by the Department in 1991 and was funded in Fiscal 1992 at $65 million.[340] Continuation funding for Fiscal 1993 is anticipated. Healthy Start is administered by the Health Resources and Services Administration (HRSA) within the Public Health Service.

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[338] § 301 of the Public Health Service Act. 42 USC § 241.

[339] § 1115 of the Social Security Act.

[340] A notice of the new demonstration was published in the Federal Register on April 17, 1991 (56 Fed. Reg., 15796). For Fiscal 1991 $25 million in funding was made available. It was anticipated that $171 million would be appropriated for Fiscal 1992. However, in order to appropriate funding at this level, the President sought reductions in funding for other programs aimed at reducing infant mortality, including the Community and Migrant Health Centers programs and the Title V Maternal and Child Health Services Block Grant. These proposed reductions were not enacted, but additional funds were appropriated to continue the President's initiative.

There are no program-specific regulations for Healthy Start. However, program guidance[341] states that the purpose of the demonstration is to "develop new and innovative means of delivering services to meet the needs of pregnant women and infants" in order to reduce infant deaths in very high mortality areas.

Because of the impact 'of inadequate immunization on infant mortality and morbidity, the Department anticipates that access to immunizations and other forms of primary health.care, will be an integral feature of the demonstration sites.[342]

HRSA expects that Healthy Start funds will be used to promote access to health services without paying for them directly, except in highly unusual circumstances. A central assumption of the program is that within communities there potentially exist adequate resources to reduce infant mortality and that these resources can achieve improved outcome through better planning, integrated service design, and innovative service delivery arrangements. Thus, sites are expected to utilize existing resources, such Medicaid, Title V, community health centers and other programs that pay for or furnish immunizations and other services,[343] rather than pay for immunization services directly with their demonstration funding. Indeed, total demonstration funding levels for the 15 sites -- approximately $3 million per site -- are too modest to permit the use of Healthy Start monies for any significant amount of direct service delivery.

Given the fact that improved access to immunizations is a goal of the demonstration, a key component of the evaluation should be an analysis of the extent to which the demonstration affects infants' immunization status. Within the evaluation, separate analyses will be needed, given the initiative's hypotheses. Some of the most important are:

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[341] 56 Fed. Reg., op. cit. at p. 15797.

[342] Guidance issued on May 6, 1991, by the Health Resources and Services Administration specifically identifies immunizations as a demonstration service. In all, fifteen urban and rural communities were chosen as demonstration sites in the fall of 1991. They are located in Washington, D.C., Baltimore, Maryland, Boston, Massachusetts, New York City, Cleveland, Ohio, Detroit, Michigan, Gary, Indiana, New Orleans, Louisiana, the North Plains Indian Community in South Dakota, Iowa and Nebraska, Oakland, California, the Pee Dee Region of eastern South Carolina, Philadelphia, Pennsylvania, Pittsburgh, Pennsylvania, and Birmingham, Alabama.

[343] **Unpublished Guidance for the Healthy Start Program, Health Resources and Services Administration, May, 6, 1991, at p. 3.**

- an analysis of the types of immunization barriers that were identified by applicants/grantees during the planning and service delivery phases of the project;

- an analysis of the extent to which modifications in financing and service delivery were made in order to remove or lessen barriers; an evaluation of whether, in fact, immunizations resources provided to be sufficient;

- an evaluation of the types of problems that arose as grantees attempted to better integrate programs paying for and furnishing immunizations and identification of continued deficiencies in programs, if any;

- an analysis of the immunization outreach techniques which proved most effective; and

- an analysis of the degree to which changes in immunization utilization patterns were observed, and the infant health outcomes achieved.

29. PACIFIC BASIN HEALTH SERVICES INITIATIVE

The Pacific Basin Health Services initiative is a small project to test more effective means for delivering health care, particularly primary health services, to the remote U.S. island populations in the Pacific. No specific immunization standards are contained in the Basin Initiative. Since the initiative is administered by HRSA, which oversees several service delivery demonstrations, it probably is safe to assume that HRSA applies the same program expectations that pertain to similar health services activities. However, major questions arising from this initiative are whether the populations to be aided have special immunization needs, whether their language, culture and extreme isolation create any special immunization barriers, and what approaches have proven most effective in removing these special barriers.

30. RURAL HEALTH OUTREACH

The Rural Health outreach initiative has been under way since 1990. For Fiscal 1992, funding levels are set at $20 million, and there are approximately 50 funded sites. As with Healthy Start, Rural Health outreach is a PHS demonstration program and is administered by HRSA. The guidance for the Initiative does not set forth any specific immunization practice guidelines. It is assumed that general HRSA policies for other programs furnishing immunization services apply.

The purpose of the program is to test new approaches to delivering comprehensive primary health services in rural areas of the country. Key issues in the evaluation of Rural Health outreach will be the specific immunization needs of rural residents, the types of problems which arise in the delivery of immunization services under rural conditions, and service delivery models that are particularly effective.

31. PEDIATRIC AIDS HEALTH CARE DEMONSTRATIONS

The pediatric AIDS demonstrations were initiated by the Department in 1988. In Fiscal Year 1992 the demonstration received $19.7 million in federal funding.[344] The program is administered by the Bureau of Maternal and Child Health within HRSA. The target populations are children, youth, women of childbearing age and families affected by the HIV infection.[345]

As with the Healthy Start and Rural Outreach demonstrations, funding levels for the pediatric AIDS demonstrations are modest. Thus, the purpose of the demonstration is to test efficient means of coordinating existing resources for children, youth and others with HIV. Of particular importance, according to 1992 funding guidelines, are projects that coordinate funds available for pediatric AIDS through Medicaid, the Title V Maternal and Child Health Services Block Grant, Title XXVI of the Public Health Service Act (the Ryan White C.A.R.E. Act) and federal funding for hemophilia treatment.

Two of the principal service objectives of the demonstration are to improve access to preventive services in order to limit the spread of AIDS and increase access to comprehensive ambulatory care for patients with HIV. Immunizations for both infants and children and women of childbearing age are thus potentially key features of the preventive side of the demonstration.

The demonstration guidance does not set forth specific immunization expectations for demonstration grantees. However, given the importance of preventing illness to the long-term survival of AIDS patients, an evaluation of the immunization status of patients will be important. The demonstration provides potentially important information on effective techniques for serving high-risk patients and the adequacy of immunization funding and service delivery levels for high risk patient populations.

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344 P.L. 102-170 (1992).

345 57 Fed. Reg. 9132 (March 16, 1992).

32. CDC WIC and AFDC DEMONSTRATIONS

Under its demonstration authority, the Centers for Disease Control is presently conducting two demonstrations in Chicago, Illinois and Dallas, Texas, to test means of improving the immunization status of WIC beneficiaries and of using WIC more effectively to deliver immunization services. The CDC is also testing methods for more effectively reaching AFDC recipients with demonstration sites in New Jersey and Alabama.

Neither demonstration involves a reduction in benefits. The WIC demonstration provides recipients with food vouchers for periods of two and three months if they can demonstrate that their children are up-to-date on their immunization status. Normally vouchers are dispensed on a monthly basis only.

In the New Jersey AFDC demonstration, a public health nurse is stationed at a local welfare agency in order to be able to immunize children on the spot. The objective of the project, in the words of a CDC official, is to place additional immunization capacity in the most underserved communities and to test the results of doing so. The project is designed so that families virtually cannot leave without having their children checked.

The Alabama demonstration will entail stationing immunization "trackers" in welfare offices in three counties, in health departments in two counties, and nowhere in one control county. The goal of the project is to determine whether it is more effective to check on immunization status in welfare offices, health departments or not at all.

33. IMMUNIZATION DEMONSTRATION INVOLVING REDUCTION IN AFDC BENEFITS

In 1992, the Secretary approved an application for demonstration authority to test a sanctions approach to improve the immunization status of children in AFDC households. The demonstration is overseen at the federal level by the Office of Family Assistance within the HHS Administration for Children and Families and is being carried out under the Social Security Act's general demonstration authority.[346]

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[346] Section 1115 of the Act, 42 USC S 1315 (1992). This provision permits the Secretary to waive otherwise applicable requirements of Social Security Act state grant in aid programs (including AFDC, Medicaid, and other programs) to conduct demonstrations that further the objectives of the Act. See, generally, S. Rosenbaum, "Mothers and Children Last: The Oregon Medicaid Experiment" American Journal of Law and Medicine (Summer, 1992).

Generally, the Social Security Act prohibits states from

As a sanctions project, this demonstration is virtually the mirror image of the CDC projects. Thus, it is important that the CDC and OFA demonstrations be evaluated in tandem.

The demonstration authorizes the State of Maryland to impose otherwise impermissible fiscal sanctions on AFDC families in the form of reduced assistance grants. These sanctions are to be imposed if family members fail to meet certain specified requirements pertaining to education and training, school attendance and the use of preventive health services. One of the preventive health services whose utilization is to be monitored under the demonstration is immunizations for preschool age children.

Under the terms of the demonstration, (which was been given an approved starting date of July, 1992, and is to be continued for five years) the Maryland AFDC agency is permitted to withhold $25.00 per month per child for every pre-school child who does not meet the minimum standards for the Medicaid EPSDT program, including being up-to-date on EPSDT immunization services.[347] Thus, a mother with two preschool age children, who is now entitled $396.00 per month can be sanctioned up to $50.00 per month (approximately a 12 percent reduction in AFDC payment levels) if both children cannot show up-to-date immunization records. The objective of the Social Security Act which this aspect of the demonstration seeks to achieve is greater utilization of Medicaid EPSDT services.

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imposing conditions of eligibility on beneficiaries other than those specifically permitted under federal law or to sanction beneficiaries for acts or omissions not recognized under federal law. Thus, since federal AFDC law currently does not link immunization status to the receipt of AFDC, in order for a state to require immunization as a condition of eligibility for AFDC or to sanction recipients for not being immunized, demonstration authority is required.

Once demonstration authority is granted under Section 1115, a state continues to receive federal assistance as if it were in normal compliance with the terms of the Social Security Act. Through Section 1115, a wide range of state AFDC and Medicaid demonstrations have been conducted-over the past 30 years without Congressional modification of generally applicable federal provisions of law.

[347] All AFDC recipients are entitled to medicaid. A mandatory Medicaid services for all children under age 21 is Early and Periodic Screening Diagnosis and Treatment (EPSDT), which is discussed more fully in Chapter 6. One EPSDT service is medically necessary immunization services.

In evaluating the results of the demonstration, a central issue is whether the threat of significant financial sanctions leads to greater use of preventive health services among low income patients. However, the state's May, 1992, application contains no specific information regarding the basis for the state's hypothesis that the use of sanctions can result in health utilization changes. Neither does the application contain information regarding the availability of immunization and preventive health services for Medicaid beneficiaries in the demonstration areas.[348]

Finally, the application contains no information evaluating the capacity of beneficiaries to use those services that are available.%'

The application does note that 57 percent of children who are entitled to EPSDT services do not use them. Presumably, additional information regarding the reasons for children's non-use of EPSDT services will be included in the formal evaluation methodology, This methodology had not been submitted at the time the application was approved; its submission was required within 60 days of the approval date.

In short, the lack of information about the outcomes of past and similar immunization or preventive health research efforts indicates that Maryland demonstration may test a novel hypothesis regarding how barriers to children's immunization services can be reduced, at least in the case of children living in households receiving direct need-based government assistance under AFDC. The program's evaluation design and results are of potentially major importance to future federal immunization policy.[350] Moreover, because the sanction imposed in this instance is a relatively

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[348] Presumably Maryland's Medicaid beneficiaries' face health care barriers not dissimilar to those that have been identified for Medicaid beneficiaries nationally in numerous studies. See, generally, Physician Payment Review Commission, Report to Conaress. 1992 (Washington, D.C.)

[349] Studies on use of preventive health services among Medicaid children indicate that Medicaid-enrolled children are as likely as privately insured children to make use of preventive health services. See, e.g., Rosenbach, Margo, and St. Peter, et al. Thus, to the extent that Medicaid enrolled children are not using immunization services, the accessibility and availability of the service itself may be as great a factor (or even a greater one) than the willingness of beneficiaries to use the services.

[350] Indeed, the Bush Administration, prior to its approval of the Maryland demonstration, had indicated an interest in testing **the relationship between childhood immunization status and financial sanctions on AFDC families.**

sizable reduction in subsistence income, it is extremely important that the evaluation test the positive outcomes of the demonstration against its potentially adverse consequences.[351]

34. MEDICARE PREVENTIVE HEALTH DEMONSTRATION

As part of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA)[352] Congress instructed the Secretary to undertake preventive health services demonstrations for Medicare beneficiaries. The statute expressly defines immunizations as one of the preventive services under the demonstration. The demonstrations are to be four years in length and must be carried out in at least five sites.

The 1987 demonstration provisions represent a continuation of an earlier administrative demonstration of the effectiveness of preventive health services that was instituted by the Department in 1983.[353] With the exception of hepatitis B and pneumococcal pneumonia immunization, Medicare currently does not cover immunization services.

The Health Care Financing Administration oversees both Medicare and the Medicare demonstrations. The agency has indicated that evidence of the cost effectiveness of both immunizations and other preventive services for older and'disabled adults[354] is based on expert opinion from such groups as the CDC Advisory Committee on Immunization Practices rather than on scientific evidence. Thus, the results of the earlier demonstration apparently have not yet led the agency to recommend full immunization coverage under Medicaid for other recommended immunizations for older persons.

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[351] The application does not indicate that beneficiaries can avoid the sanctions through a showing that services were sought but not available or that loss of funds would lead to harmful consequences, such as the loss of a home or the denial of other essential subsistence needs. Presumably these consequences will be explored during the evaluation process, particularly since , as with all HHS funded experiments involving human subjects, the Maryland 1115 demonstration must adhere to certain minimum standards. See "Mothers and Children", op. cit.

[352] § 9314, P.L. 99-272 (1986).

[353] 52 Fed. Reg. 20147 (May 29, 1987).

[354] Several hundred children are entitled to Medicare because they have end stage renal disease. These children receive the same Medicare benefits as other beneficiaries. Thus, they are not entitled to immunizations of proven effectiveness for children. It is unclear whether any of the demonstrations under COBRA involve ESRD children.

HCFA intends to collect data on both short-term and long-term cost savings to the program, as well as changes in service utilization patterns.

COBRA demonstration grants have been awarded to five schools of public health, including Johns Hopkins University, San Diego State University, the University of California at Los Angeles, the University of Pittsburgh, and the University of Washington.[355] Each demonstrations involves an experimental groups of Medicare beneficiaries which is offered a special package of Medicare preventive services, as well as a control group which is not. Services were furnished to the experimental groups from May, 1989 through April, 1991. An interim report is due to Congress in 1993, with a final report in 1995.

To the extent that HCFA is correct in assuming that past studies of immunization do not yet form a sufficiently solid scientific basis for financing all recommended vaccine services for older and disabled adults, the results of this demonstration are highly important. To the extent that the basis for concluding that such services are effective and cost efficient exist, the demonstrations are nonetheless highly important for determining whether amendments to Medicare constitute the most effective means for assuring access to immunization services. For example, if Medicare beneficiaries in the experimental group encounter difficulties in obtaining service immunization services from providers, it may be that other forms of paying for immunizations for beneficiaries (e.g., through direct grants to local health agencies and agencies on aging) may be more effective.

[355] Information from the Health Care Financing Administration, July, 1992.